EXHIBIT B

US006203569B1

(12) **United States Patent**
Wijay

(10) **Patent No.: US 6,203,569 B1**
(45) **Date of Patent: *Mar. 20, 2001**

(54) **FLEXIBLE STENT**

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(*) Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **08/883,801**

(22) Filed: **Jun. 27, 1997**

Related U.S. Application Data

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(51) **Int. Cl.**[7] **A61F 2/06**
(52) **U.S. Cl.** **623/1.15**; 623/1.16; 623/1.17
(58) **Field of Search** 623/1, 11, 12, 623/1.15, 1.16, 1.17

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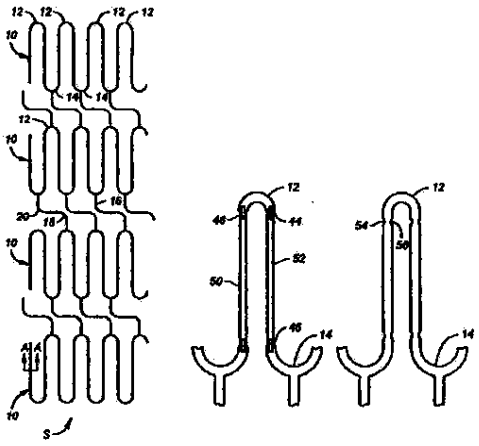
(57) **ABSTRACT**

A stent is disclosed which comprises generally of ring having, in the preferred embodiment, crossties that have flexibility by having at least one bend. The rings themselves have predetermined stress-relieving points to predispose, by stress relief, particular segments of each ring to bend upon application of an expansion force such as by a balloon or by other means. In the preferred embodiment, the individual rings have notches, reducing the cross-sectional areas at particular locations adjacent reversing bends such that upon radial expansion, bending occurs at these reduced cross-sectional areas to prevent stress from accumulating at the reversing bends.

26 Claims, 4 Drawing Sheets



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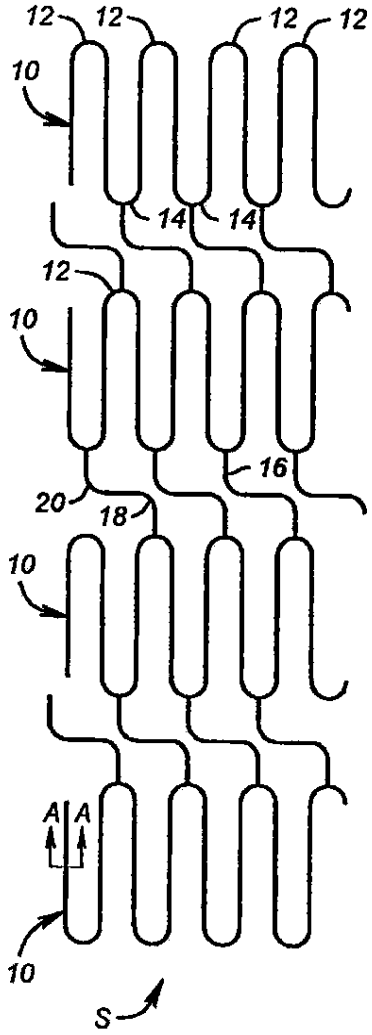

FIG. 1

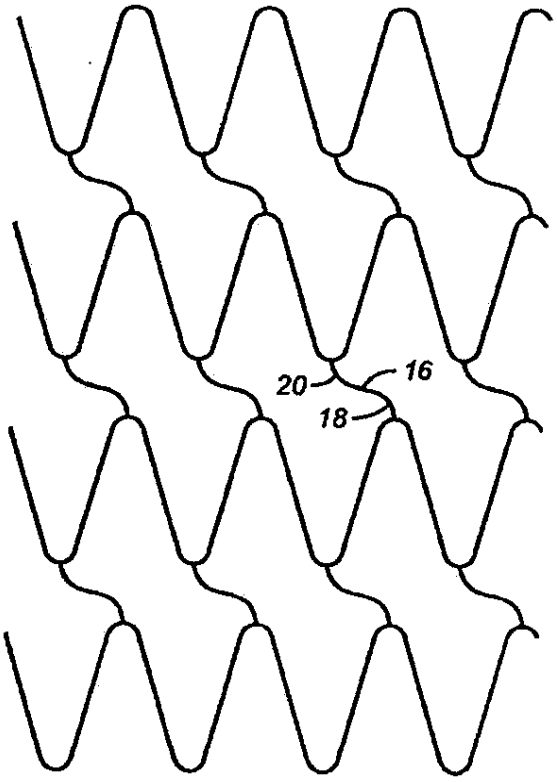

FIG. 2

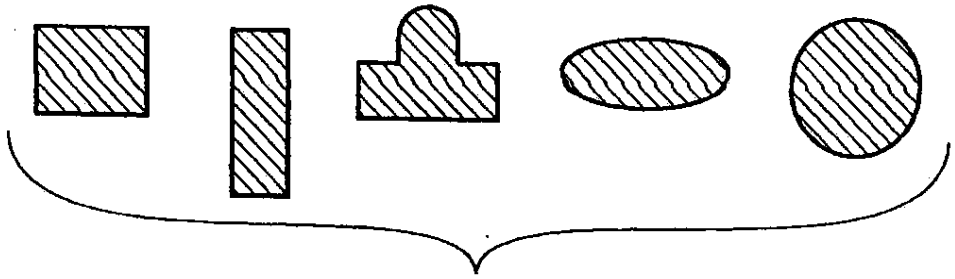

FIG. 3

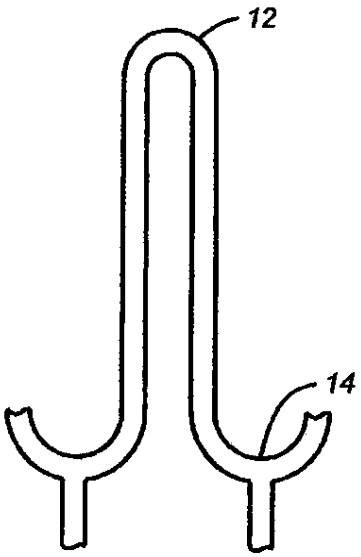

FIG. 4

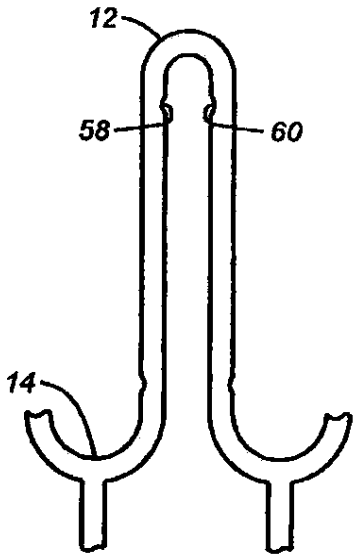

FIG. 5

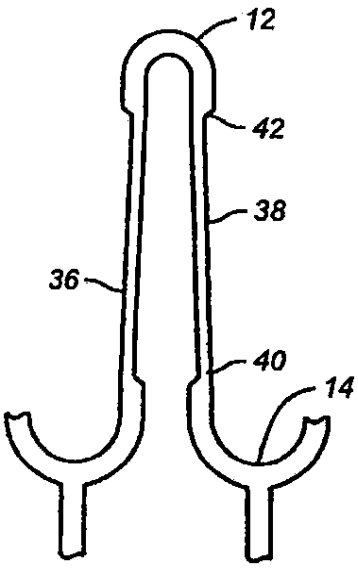

FIG. 6

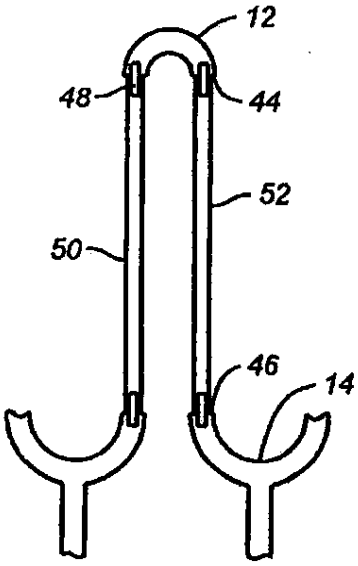

FIG. 7

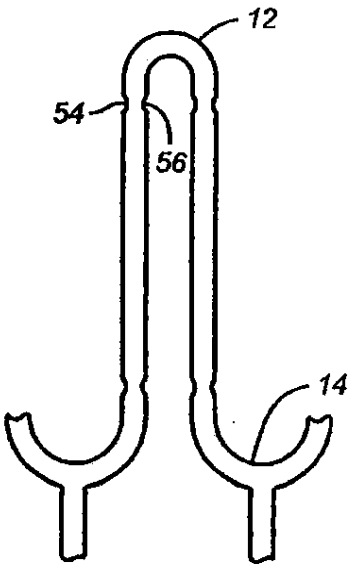

FIG. 8

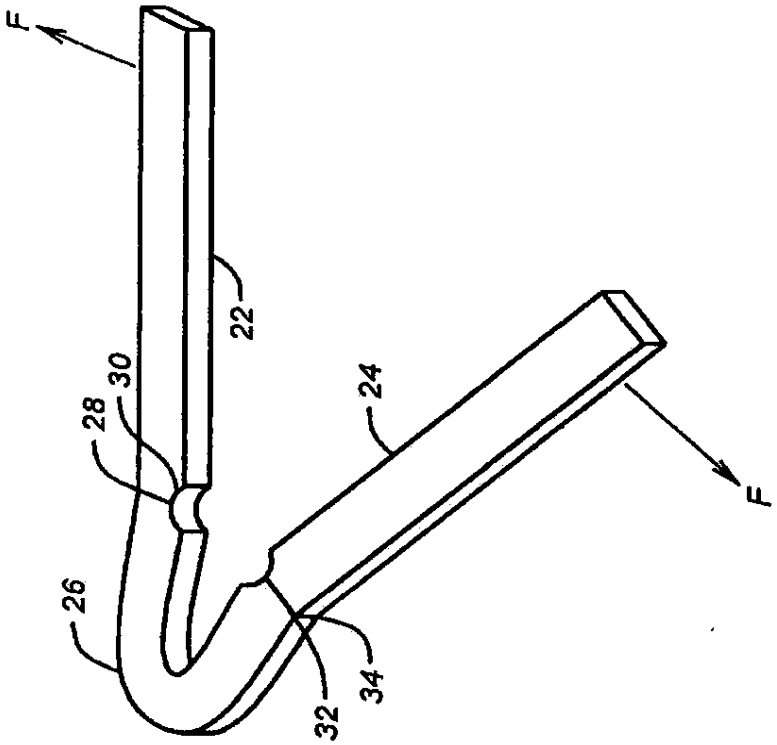

FIG. 10

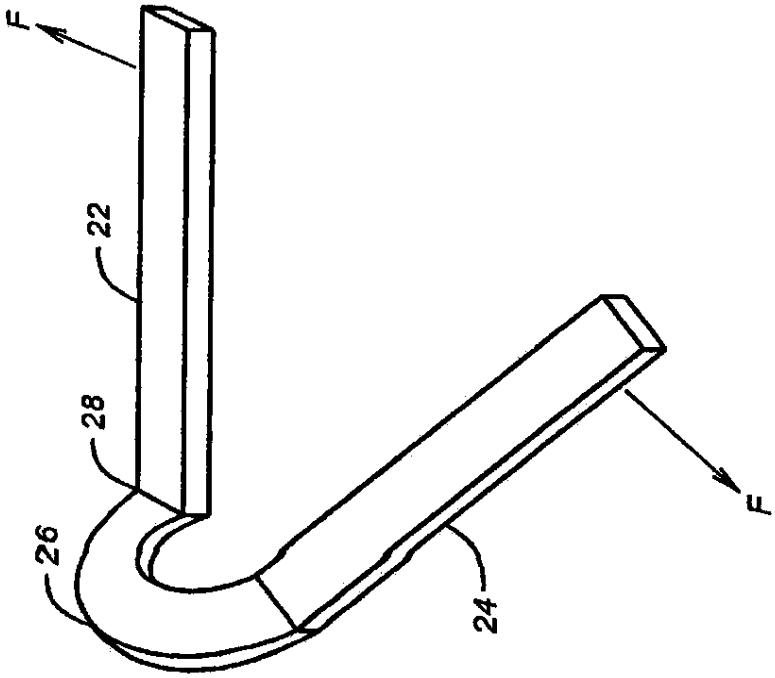

FIG. 9

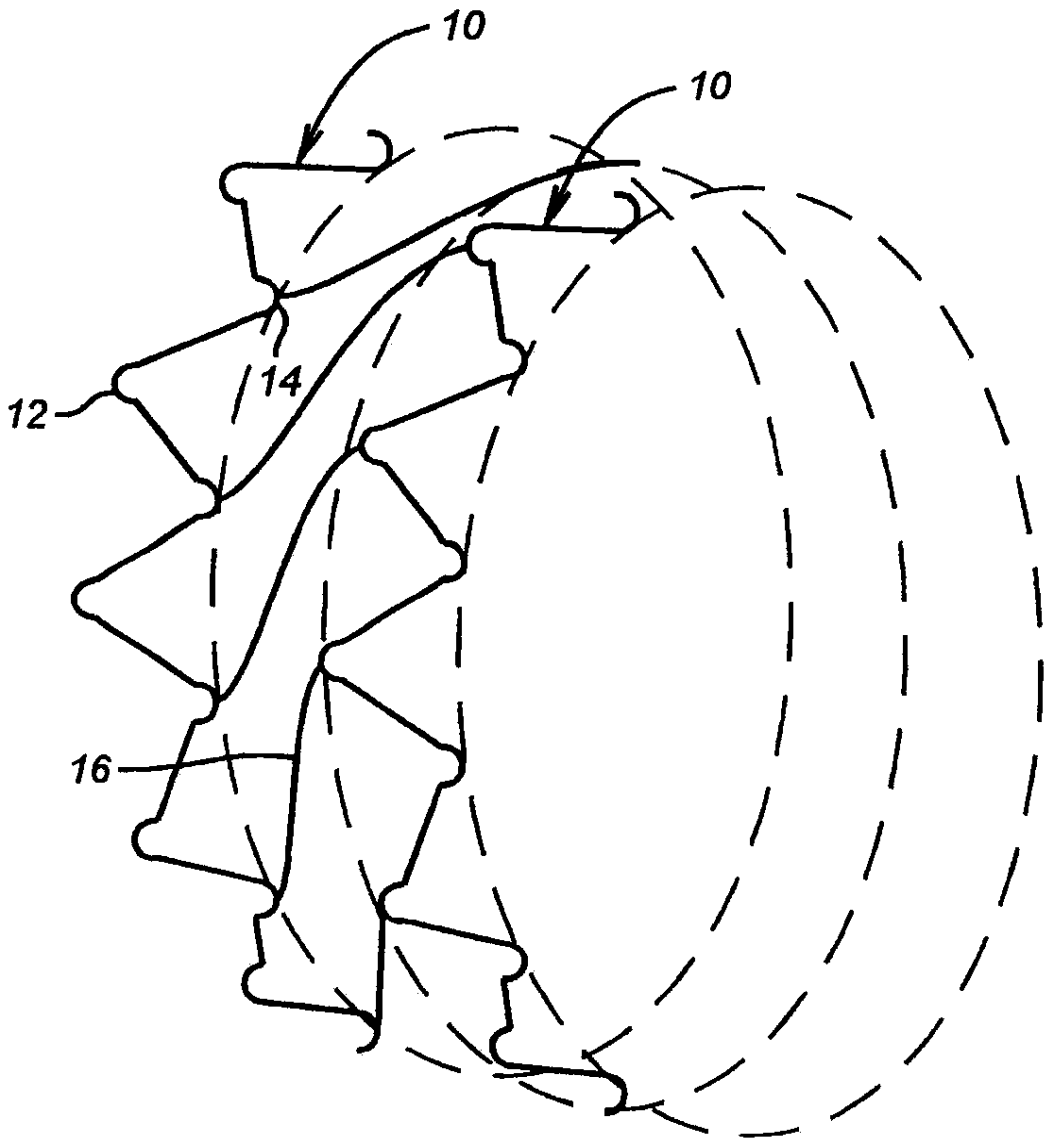

FIG. 11

FLEXIBLE STENT

This application is a continuation of copending application Ser. No. 08/582,657, filed on Jan. 4, 1996.

FIELD OF THE INVENTION

The field of this invention relates to vascular stents that can be delivered to a predetermined position and allowed to spring outwardly or, in the alternative, which can be expanded in place.

BACKGROUND OF THE INVENTION

Vascular stents are structures that are designed to maintain the patency of a vessel in the body. The stent provides internal support to allow the circulation to proceed therethrough. Stents can be used in the vascular system in ureters, bile ducts, esophagus, and in many other tubular structures in the human body.

Stents can be tubular or can be made from wire. Stents are typically made from a metal or polymeric substance or a metal coated with polymers which are biocompatible or contain heparin to reduce blood clotting or other tissue reactions. Many prior designs have used a coil approach where a wire is helically wound on a mandrel. Yet other designs have evolved—braided wire mesh and angulated wire forms wrapped on a spindle to form a coil.

U.S. Pat. No. 5,292,331 by Boneau and U.S. Pat. No. 5,403,341 describe such wire forms. These devices have very poor radial support to withstand the hoop strengths of the artery or vein and further are not suitable for arteries that are bent or curved or for long lesions; multiple stents are required. These designs do not provide any support to hold the wall of the artery, other than the memory of the metal.

Wall Stent, produced by Pfizer Inc., is a braided wire tube. Although this stent is flexible so as to be placed in curved arteries or veins and other body cavities, it does not have any radial strength imparted to it by design.

Wiktor, U.S. Pat. No. 4,649,922; 4,886,062; 4,969,458; and 5,133,732 describe a wire form stent. He describes stents made of wire helix made of a preformed wire which is in the sinusoidal form, in which either all or some of the adjacent strands are connected.

Arthus Fontaine, U.S. Pat. No. 5,370,683, also describes a similar device where a flat wire form of sinusoidal shape is wound on a mandrel to form a helical coil. the wire bends are "U" shaped and are connected to alternate "U"-shaped bands.

Allen Tower, U.S. Pat. Nos. 5,217,483 and 5,389,106 describes a similar device where the wire is preformed to a sinusoidal shape and subsequently wound on a mandrel to form a helical coil.

All of the above-described art fails to provide radial support. The pre-shaped wire form (sinusoidal in most of the prior art) is wrapped on a mandrel to form a coil. However, the forces imported by the vessel wall's hoop strength are radially inward. In other words, the force is acting perpendicular to the plane of the U-shaped wire form. This means that the bends that are in the wire add no structural strength to the wire form to support the force produced by the wall, which is radially inward.

When we examine the simple coils, such as taught in Scott U.S. Pat. No. 5,383,928 or Gene Samson U.S. Pat. No. 5,370,691 or Rolando Gills U.S. Pat. No. 5,222,969, it is apparent that the spring coil will withstand substantial radial forces due to the vessel wall; however, all these stents are

bulky in their pre-expanded form and are hard to place in small and curved arteries or veins of the body. Also, a major disadvantage of this design is that when the coil stent is placed in a curved artery or vein, it forms an "accordion" shape whereby some strands in the outer radius are spread and those of the inner radius are gathered. Spring coils can also "flip" to form a flat structure when a longitudinal force is applied on one side of the stent.

The other types of stents that have been developed are tube stents. Palmer, U.S. Pat. No. 4,733,665; 4,739,762; 7,776,337; and 4,793,348 describe such a tube stent of slotted metal tube. The slotted metal tube is expanded by a high-pressure balloon to implant the stent into the inside wall of the artery or vein.

Joseph Weinstein, U.S. Pat. No. 5,213,561 describes a similar stent made of tubular materials with slots cut into it. On expansion using a balloon, it forms a structure with diamond-shaped slots.

Henry Wall, U.S. Pat. No. 5,266,073 also describes a stent, tubular, that has slots machined into it. When expanded, the edges of the stent lock to form a cylinder. Not only is this device stiff and can only be used for short lesions, but also the diameter cannot be adjusted to meet the exact needs of the particular vessel but it is fixed to the predetermined sizes.

Lau and Hastigan, U.S. Pat. No. 5,344,426 describes a slotted tubular stent that has a structure similar to Henry Wall's but has provided prongs that will lock in as the stent is expanded.

Michael Marin, U.S. Pat. No. 5,397,355 also describes a tubular slotted stent with locking prongs.

U.S. Pat. No. 5,443,500 illustrates the use of square openings with rectangular prongs that stick therethrough to lock the stent. This design, as well as other locking mechanisms, generally have resulted in very stiff stents because of the use of a tubular-type grid construction. Further, the locking devices have resulted in sharp outwardly oriented tabs which are used for the locking, which could cause vascular damage.

All the above-described tube stents, although typically providing substantial radial support when expanded, are not flexible enough to be placed in curved vessels. Arteries and veins in the human body are mostly curved and are tapered. As such, these tube stents suffer from this main disadvantage.

European patent document 042172982 employs wires that are doubled up and whose ends are snipped off to make a given joint. Such doubling up at the junction of two elements with snipped off free ends creates a potential puncture problem upon radial expansion. The sheer bulk of the doubled up wires makes them rotate radially outwardly away from the longitudinal centerline of the stent, while the plain ends on such an arrangement which are snipped off offer the potential of sharp points which can puncture or damage the intima. On the other hand, the apparatus of the present invention, employing sharp angles, as defined, avoids this problem in an embodiment which illustrates a continuous wire or wire-like member bent into a sharp angle. This type of structure alleviates the concerns of sharp edges, as well as the tendency of a doubled up heavy joint to rotate outwardly toward the intima upon radial expansion of the stem, as would be expected in the EPO reference 042172982.

Often these stents are layered with polymeric sheaths that are impregnated with biocompatible substances or can be coated with heparin or hydrogel. Most sheath-type coatings

reduce endothelial cell growth through the stent, which is a major requirement in successful stenting of body cavities such as arteries and veins.

Several parameters in design of stents are important. Of the more important parameters is the issue of recoil. Recoil deals with the memory of the stent material which, generally speaking, upon expansion in the blood vessel will want to recoil back to its original shape. This can be problematic because it is desirable for the stent, once expanded, to remain in good contact with the vessel wall to avoid longitudinal shifting. Furthermore, any recoil constricts the flow passage and presents a greater portion of the stent in the blood flowpath, thus creating additional complications due to the turbulence which ensues.

Related to the concern regarding recoil is another concern regarding component twist. This phenomenon generally occurs when the cross-sectional area of the components is rectangular, such as when the stent is manufactured from a cylindrical piece which is then cut by lasers or other means to form the particular pattern. Particularly in the honeycombed designs involving the use of square or rectangular element cross-sections, radial expansion of such stents generally results in a twist of the component segments such that they extend into the flowpath in the artery or vein. Again, this causes turbulence which is undesirable.

Related to the problem of recoil or constriction after expansion is the ability of the stent to anchor itself in the vascular wall. An anchoring system that does not cause trauma is a desirable feature not found in the prior art.

Yet other considerations which are desirable in a stent not found in the prior art is the flexibility to be maneuvered around bends in the vascular system, coupled with the ability to conform to a bend without kinking or leaving large open areas. The stents of the present invention have the objective of addressing the issue of recoil, as well as providing an anchoring mechanism to fixate the stent once set. Several of the designs incorporate flexibility to allow the stent to follow a bend or curve in a vascular flowpath while a the same time providing sufficient radial deformation to ensure proper fixation while minimizing angular twisting movements of the stent components to minimize turbulence through the stent.

In a recent article appearing in late 1995, by Dr. Donald S. Baim, entitled "New Stent Designs," a description is given of the ideal endovascular prosthesis. There, Dr. Baim indicates that the ideal stent should have low implantation profile with enhanced flexibility to facilitate delivery. He goes on to say that the stent should be constructed from a noncorrosive, nonthrombogenic radiopaque alloy and have expanded geometry which maximizes radial strength to resist vascular recoil. The ideal stent described by Baim is further described as having a wide range of diameters and lengths. Dr. Baim concludes that it is unlikely that any current designs satisfy all these requirements. Thus, one of the objectives of the present invention is to go further than the prior designs in satisfying the criteria for the ideal designs as set forth by Dr. Baim in his recent article.

SUMMARY OF THE INVENTION

A stent is disclosed which comprises generally of ring having, in the preferred embodiment, crossties that have flexibility by having at least one bend. The rings themselves have predetermined stress-relieving points to predispose, by stress relief, particular segments of each ring to bend upon application of an expansion force such as by a balloon or by other means. In the preferred embodiment, the individual rings have notches, reducing the cross-sectional areas at particular locations adjacent reversing bends such that upon radial expansion, bending occurs at these reduced cross-sectional areas to prevent stress from accumulating at the reversing bends.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates the stent of the present invention in an unrolled condition prior to expansion.

FIG. 2 is the stent shown in FIG. 1 in an unrolled condition after expansion.

FIG. 3 is a section along lines A—A of FIG. 1 and illustrates several different cross-sectional shapes that can be used for the stent illustrated in FIG. 1.

FIG. 4 is a detailed view of the stent in FIG. 1, shown without any cross-sectional changes to the undulating design of the ring structure illustrated in FIG. 1.

FIG. 5 is similar to FIG. 4 except that it employs singular notches adjacent reversing bends.

FIG. 6 employs a change in the cross-sectional shape taking place adjacent each reversing bend.

FIG. 7 illustrates a joint involving a transverse tab adjacent the reversing bends.

FIG. 8 involves opposed notches on each side of the wire adjacent a reversing bend.

FIG. 9 illustrates what occurs on radial expansion of each of the rings without the use of a stress-relief mechanism such as a notch or a cut-out.

FIG. 10 illustrates the action upon radial expansion using a notch and its effect on the reversing bend.

FIG. 11 is a perspective view of the stent shown in FIG. 2 in the expanded position.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. 1 shows, in flattened out form, a stent S which is unrolled along its longitudinal axis. The stent S has a series of rings **10** which are preferably of a wire material (preferably stainless steel, nickel-titanium alloys, tantalum alloys) bent in a series of reversing undulations **12** and **14**. The wire can be coated with polymer such as polyethylene, polytetrafluoroethylene (Teflon®), or polylactates containing heparin or drugs or radioactive material. The bends **12** may have a similar radius or may vary as among bends **12** or as among bends **14**. In other words, each of the bends **12** may be identical to each other. Each of the bends **14** may be identical to each other. Each bend **12** may be identical to each bend **14**. One bend **12** can be different from another bend **12**, which is in turn also different from another bend **14**, or any combinations of the above. While rounded bends are shown as **12** and **14**, other shapes can be used to create a generally undulating pattern, such as sharp bends which generally form a V-shape. Connecting each row **10** is one or more crossties **16**. In the preferred embodiment, the crossties **16** have flexibility in that they have at least one bend **18**, while a double bend, such as including **18** and **20**, is preferred for the construction of the crossties **16**. One or more crossties can be used which connect a bend **14** to its opposing bend **12**. Thus, as shown in FIG. 1, the crossties **16**, looking from bottom to top, make a bend to the left and a bend to the right on their way from reverse bend **12** to a reverse bend **14**. One or more crossties **16** can be used between rings **10** up to a maximum where every reversing bend, such as **14**, is connected to an adjacent but offset circumferentially reversing bend **12**.

FIG. 2 illustrates the stent S in a radially expanded form, illustrating that the crossties 16 continue to retain flexibility because of the reversing bends 18 and 20. Thus, the longitudinal flexibility of the stent S is retained, even in the expanded position. The use of the crossties with, at minimum, a single bend gives them flexibility. The design involving rings 10 connected by crossties 16 prevents stiffness experienced in some prior designs that had a particular longitudinal segment with undue stiffness giving the stent S a "backbone," thus making it unduly stiff longitudinally. Use of the flexible crossties 16 also provides flexibility for relative rotation between rings 10 while the expansion is taking place. Flexibility is also provided in the longitudinal direction as the crossties 16 may elongate in that direction without putting the stent S into a kink or a longitudinal bind.

FIG. 3 illustrates alternative cross-sectional shapes for the wire cross-section which makes up each of the rings 10 and/or the crossties 16. Thus, FIG. 3 illustrates squares, rectangles, circles, ovals, and composite shapes.

One of the concerns with an undulating structure, such as illustrated in FIG. 1, is the reversing bends 12 or 14, unless some provisions are made, experience undue stress and are even prone to bending out of their plane when the stent is radially expanded. This phenomenon is illustrated in FIG. 9. There, a pair of straight segments 22 and 24 are joined together by a reversing bend 26. As illustrated in FIG. 9, the cross-sectional area of the segments 22 and 24 are rectangular, one of the shapes shown in FIG. 3. It should be noted that other cross-sections, apart those illustrated in FIG. 3, can be used without departing from the spirit of the invention.

With no significant cross-sectional change occurring at the transition or near the transition 28 between the reverse bend 26 and the segments 24 or 22, the stress is transferred to the reverse bend 26 when an expansion force F tries to radially expand the stent S by moving segments 22 and 24 apart. Depending on the amount of stress induced, a bending occurs, as shown in FIG. 9, where the reverse bend 26 bends out of plane so that it is no longer in alignment with the segments 22 and 24, which was its condition prior to the application of force F.

FIG. 10 shows the contrast of the behavior of the reverse bend 26 when a notch 30 is placed adjacent the transition 28 between the reverse bend 26 and the segment 22 and a similar notch 32 is placed near transition 34 between the reverse bend 26 and the segment 24. What results is a reduced cross-sectional area at transitions 28 and 34. Thus, when force F is applied to the segments 22 and 24, there is a permanent bending occurring at the zone of least cross-sectional area, i.e., transitions 28 and 34, with their respective notches 30 and 32. Accordingly, the stress from radial expansion of a ring 10 as illustrated in FIG. 1 is absorbed by a bending or deformation at the transitions 28 and 32, thus minimizing if not eliminating the applied stress to the reverse bend 26 after radial expansion of the stent S by expanding all of the rings 10. This type of structure illustrated in FIG. 10 can be employed in the unrolled stent shown in FIGS. 1 and 2.

Other alternative mechanisms for reducing the stress at the reverse bend are illustrated in FIGS. 5–8. It should be noted that the features illustrated in FIGS. 5–8 are to be found in the stent shown in FIGS. 1 and 2; however, in order to show the overall layout of the stent S, FIGS. 1 and 2 are not sufficiently magnified so that these details can be seen. However, FIGS. 5–8 represent a greater magnification of adjacent reverse bends, such as 12 and 14.

In FIG. 6, the connecting segments 36 and 38 have a smaller cross-sectional area than the cross-sectional area at the reverse bends 12 and 14, thus creating zones of transition of cross-section 40 adjacent reverse bend 14 and 42 adjacent reverse bend 12. This construction is typical for each of the rings 10 of a particular stent. It should be noted that the various features illustrated in FIGS. 5–8 can be used uniformly throughout the stent or mixed and matched for a desired effect.

The detail in FIG. 7 illustrates a cross-sectional area transition point 44 and 46, respectively adjacent reverse bends 12 and 14. Here, there is not only a transition cross-sectional area but transverse tabs 48 are used to secure the joint between segments 50 and 52, which have a smaller cross-sectional area than the cross-sectional area of reverse bends 12 and 14.

FIG. 8 illustrates the use of opposed notches 54 and 56 adjacent the entrance and exit to each reverse bend 12 and 14. FIG. 5 illustrates the use of similar notches 58 and 60 at the entrance and exit of each reverse bend 12 and 14. The difference between FIG. 5 and FIG. 8 is that in FIG. 8, the notches 54 and 56 oppose each other at the entrance and exit of each reverse bend 12 or 14, while in FIG. 5 the notches can be interiorly located, as shown in FIG. 5, or in the alternative, exteriorly located at the entrance and exit to each reverse bend 12 and 14. It should be noted that the changes in cross-sectional area do not need to be literally at the point of transition between the rounded portion of a reverse bend 12 or 14 and the straight segment which adjoins the reverse bends. However, the preferred location is at that transition. Locating the cross-sectional area change before entering the transition from the straight segment to the curved segment is also possible, depending on the degree of stress relief desired.

FIG. 11 illustrates the stent S shown in unrolled form in FIGS. 1 and 2 in a perspective view after radial expansion. It should be noted that the crossties 16 retain their flexibility, even after expansion, and that the reverse bends 12 and 14 have not buckled out of the cylindrical surface defined by the expanded stent S shown in FIG. 11. The buckling feature, which can occur in prior designs without the stress relief mechanism, is illustrated in FIG. 9.

FIG. 4 illustrates that it is within the purview of the invention to use a plurality of rings 10 connected by flexible crossties 16 without the change in cross-sectional area occurring at the reverse bends 12 and 14. While the embodiments in FIGS. 5–8 are preferred, it is within the purview of the invention to provide a stent with a multiplicity of rows 10 of undulating wire components which are connected by one or more crossties 16, each of which have at least one bend so that upon radial expansion into the position shown in FIGS. 2 and 11, the crossties 16 continue to retain flexibility in at least one but preferably more directions. Thus, the individual rings 10 have longitudinal flexibility and may rotate to some degree with respect to each other, all to conform to the tortuous path in which the stent S may be placed. By adding the change in the cross-sectional area feature, as shown in FIGS. 5–8, by using one or more of those features in a single stent, a stent is produced that is flexible, yet when expanded, retains its flexibility and is not subjected to stress to a significant degree at reversing bends after complete radial expansion. By focusing the stress occurring during radial expansion to a particular point outside the reversing bend, a simple-to-make construction occurs which addresses the concerns of some of the prior art designs which have tackled this problem by using varying degrees of curvature, such as European application No.

0662307, assigned to Advanced Cardiovascular Systems. This design, with the flexible crossties 16, represents a considerably more flexible design than rolled up coil springs such as that illustrated in U.S. Pat. No. 4,969,458. Crossties which are essentially straight, such as those illustrated in U.S. Pat. No. 5,421,955, do not afford the flexibility realized by the stent S of the present invention. It should be noted that as more bulk is presented at the transition between segments such as 22 and 24 in FIG. 9, the more likely is the bending to occur when subjected to radial expansion, as illustrated schematically by force F. Thus, designs that use doubled up wires at the apex, such as European application No. 0421729, assigned to Medtronic, exacerbate the bending results shown in FIG. 9, as well as increasing the stiffness of the stent and the force necessary for radial expansion of each of its individual rings. Additionally, by use of crossties which are coiled springs which protrude out of the cylindrical surface defined by the stent S, additional complications are created since the crossties will intrude into the vascular wall, creating additional irritation to the patient or worse damage if there is penetration of the vascular wall.

Accordingly, the above-described stent S of the present invention has the advantages of flexibility in view of the unique crossties which are used. The crossties remain in the cylindrical surface defined by the shape of the stent S, even upon radial expansion. The crossties 16 retain their flexibility, even after full radial expansion occurs. By use of the cross-sectional area changes, the applied stresses from radial expansion are focused to this transition zone as opposed to other places, such as the return bends. By focusing the deformation to the transition zone, stress is minimized or reduced in the reverse bend section, such as 12 or 14, and further the tendency of the reverse bends such as 12 or 14 to protrude out of the cylindrical surface defined by the stent S is greatly reduced, if not eliminated.

The foregoing disclosure and description of the invention are illustrative and explanatory thereof, and various changes in the size, shape and materials, as well as in the details of the illustrated construction, may be made without departing from the spirit of the invention.

What is claimed is:

1. A stent comprising:

a plurality of rings arranged in general alignment to define a cylindrical shape, each ring comprises a singular elongated wire member having discrete reversing bends which do not intersect with other reversing bends and at least two cross-sectional areas identified by at least one cross-sectional change location, said wire member forming an undulating pattern;

at least one crosstie connecting adjacent rings said crosstie disposed in general alignment with a longitudinal axis defined by said rings, said crosstie having at least one bend formed therein;

the cross-sectional area of said wire member changes adjacent at least one of said reversing bends;

said wire member which comprises each said rings, when expanded radially outwardly, bends at said cross-sectional change location adjacent said reversing bends; and

said reversing bends remain generally aligned to said cylindrical shape defined by said rings after radial expansion due to bending at said cross-sectional change locations.

2. A stent, comprising:

a plurality of rings arranged in general alignment to define a cylindrical shape, each ring comprises a singular elongated wire member having discrete reversing bends which do not intersect with other reversing bends, and at least two cross-sectional areas defined by at least one cross-sectional change location, said wire member forming an undulating pattern;

at least one crosstie connecting adjacent rings said crosstie disposed in general alignment with a longitudinal axis defined by said rings, said crosstie having at least one bend formed therein;

said wire member having at least one straight section between said reversing bends;

the cross sectional area of said wire member changes in said straight section and adjacent said reversing bends;

said wire member which comprises each said rings, when expanded radially outwardly, bends at said cross-sectional change location adjacent said reversing bends; and

said reversing bends remain generally aligned to said cylindrical shape defined by said rings after radial expansion due to bending at said cross-sectional change locations.

3. A stent, comprising:

a plurality of rings arranged in general alignment to define a cylindrical shape, each ring comprises a singular elongated wire member having discrete reversing bends which do not intersect with other reversing bends, said wire member forming an undulating pattern, said wire member having at least one cross-sectional area;

at least one crosstie connecting adjacent rings said crosstie disposed in general alignment with a longitudinal axis defined by said rings, said crosstie having at least one bend formed therein;

the wire member is formed having a notch wherein the cross-sectional area of the wire member changes at a notch location;

said notch is located adjacent at least one of said reversing bends.

4. The stent of claim 3, wherein:

said change in cross-section is accomplished by opposed notches.

5. A stent, comprising:

a plurality of rings arranged in general alignment to define a cylindrical shape, each ring comprises a singular elongated wire member having reversing bends forming an undulating pattern;

at least one crosstie connecting adjacent rings wherein said crosstie is disposed in general alignment with a longitudinal axis defined by said rings; and

said wire member is formed having a notch adjacent at least one of said reversing bends which defines a change in cross-sectional area.

6. The stent of claim 5, wherein:

said change in cross-sectional area is accomplished by opposed notches.

7. A stent, comprising:

a plurality of rings arranged in general alignment to define a cylindrical shape, each ring comprises a singular elongated wire member having discrete reversing bends which do not intersect with other reversing

bends, said wire member forming an undulating pattern; and having at least two cross-sectional areas identified by at least one cross-sectional change location; and

at least one cross-tie having said connecting adjacent rings said crosstie disposed in general alignment with a longitudinal axis defined by said rings, said crosstie having at least one bend formed between said ends to allow said crosstie to flex as said rings expand while remaining within the confines of said cylindrical shape; and

the cross-sectional area of said wire member changes adjacent at least one of said reversing bends.

8. The stent of claim 7, wherein:

said wire member changes cross-section adjacent each said reversing bend.

9. The stent of claim 8, wherein:

said wire member changes cross-section on both sides of each said reversing bend.

10. The stent of claim 7, wherein:

said wire member which comprises said rings, when said rings are expanded radially outwardly, bends at said cross-sectional change location adjacent said reversing bends.

11. The stent of claim 1, further comprising:

a plurality of non-overlapping crossties each having at least two bends.

12. The stent of claim 11, wherein:

said bends define at least two slope changes in said crossties.

13. The stent of claim 12, wherein:

each crosstie connects a reversing bend in one of said rings to the next adjacent circumferentially offset reversing bend on an adjacent ring.

14. The stent of claim 1, wherein:

said at least one crosstie comprises at least two reversing bends located remotely from said end of said crosstie.

15. The stent of claim 7 wherein:

said at least one crosstie comprises at least two reversing bends located remotely from said ends of said crosstie; and

said bends define a turn of no less than about 90°.

16. The stent of claim 15, wherein:

said crosstie having a first end offset circumferentially from a second end.

17. The stent of claim 15, wherein that portion of said crossties extending between said first and second ends and up to said bends of said crosstie are in substantial longitudinal alignment with the longitudinal axis of said cylindrical shape.

18. The stent of claim 3, wherein:

said wire-like member has straight sections between said reversing bends;

said straight sections have a smaller cross-sectional area than the cross-sectional area through said reversing bends.

19. A stent, comprising:

a plurality of rings arranged in general alignment to define a cylindrical shape, each ring comprises a singular elongated wire member having discrete reversing bends which do not intersect with other reversing bends; said wire member forming an undulating pattern and having at least one cross-section;

at least one crosstie connecting adjacent rings said crosstie disposed in general alignment with a longitudinal axis defined by said rings, said crosstie having at least one bend formed therein; and

said wire member having at least one straight section between said reversing bends;

the cross-section of said wire member changes in said straight section and adjacent said reversing bends.

20. The stent of claim 9, wherein:

said straight section has a smaller cross-sectional area than the cross-sectional area through an adjacent said reverse bend.

21. The stent of claim 19, wherein:

said wire member changes cross-section adjacent each said reversing bend.

22. The stent of claim 19, wherein:

said wire member changes cross-section on both sides of each said reversing bend.

23. The stent of claim 19, wherein:

said wire member which comprises said rings, when said rings are expanded radially outwardly, bends at said cross-sectional change location adjacent said reversing bends.

24. A stent of claim 19, further comprising:

a plurality of non-overlapping crossties each having at least two bends.

25. The stent of claim 24, wherein:

said bends define at least two slope changes in said crossties.

26. The stent of claim 25, wherein:

each crosstie connects a reversing bend in one of said rings to the next adjacent circumferentially offset reversing bend on an adjacent ring.

* * * * *

EXHIBIT C

US005733303A

United States Patent [19]

Israel et al.

[11] Patent Number: 5,733,303

[45] Date of Patent: Mar. 31, 1998

[54] **FLEXIBLE EXPANDABLE STENT**

[75] Inventors: **Henry Marshall Israel**, Baci Brak; **Gregory Pinchasik**, Hasharon, both of Israel

[73] Assignee: **Medinol Ltd.**, Tel Aviv, Israel

[21] Appl. No.: **457,354**

[22] Filed: **May 31, 1995**

Related U.S. Application Data

[63] Continuation of Ser. No. 282,181, Jul. 28, 1994, abandoned, and a continuation of Ser. No. 213,272, Mar. 17, 1994, Pat. No. 5,449,373.

[51] **Int. Cl.**[6] **A61M 29/00**

[52] **U.S. Cl.** **606/198**; 623/1; 623/12

[58] **Field of Search** 606/108, 191, 606/192, 194, 195, 198, 200; 623/1, 12

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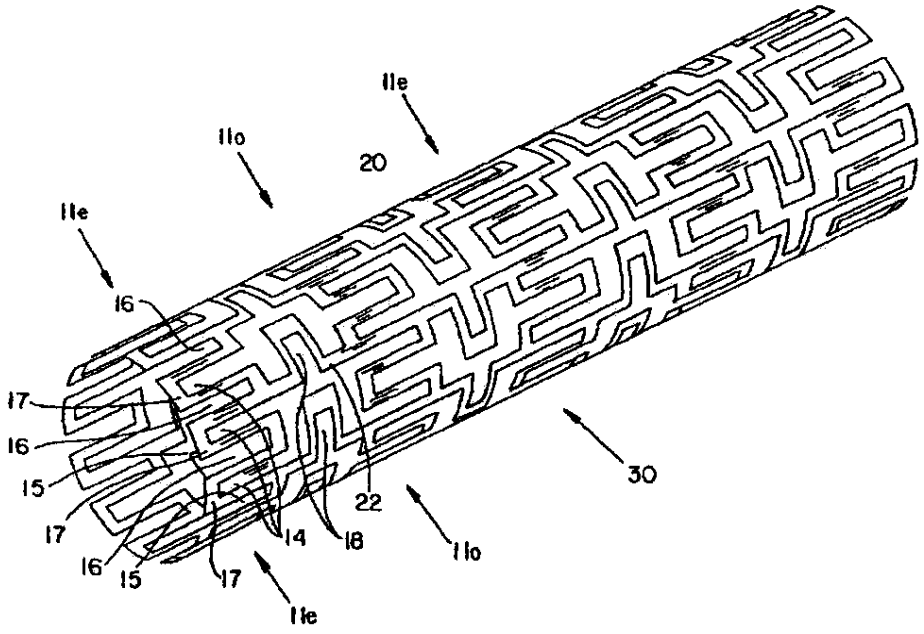
Primary Examiner—Guy V. Tucker
Assistant Examiner—William Lewis
Attorney, Agent, or Firm—Kenyon & Kenyon

[57] **ABSTRACT**

There is disclosed a stent for implanting in the body. The stent is formed of a tube having a patterned shape which has first and second meander patterns having axes extending in first and second directions. The first meander patterns can be formed into even and odd first meander patterns. The even and odd first meander patterns are 180° out of phase with each other and the odd patterns occur between every two even patterns. The second meander patterns are intertwined with the first meander patterns. The first and second directions can be orthogonal to each other. The second meander patterns can also be formed of even and odd patterns.

31 Claims, 6 Drawing Sheets



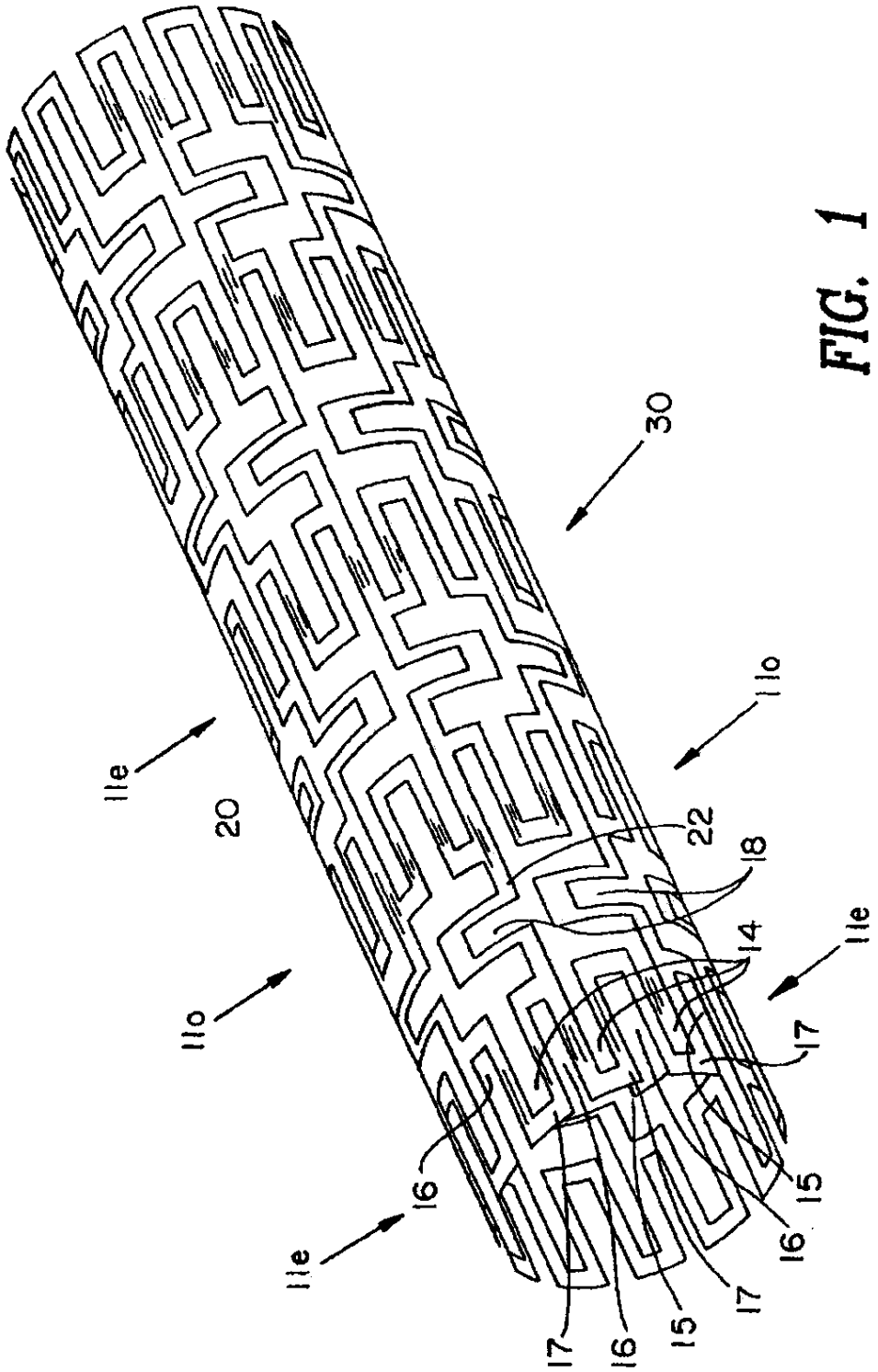


FIG. 1

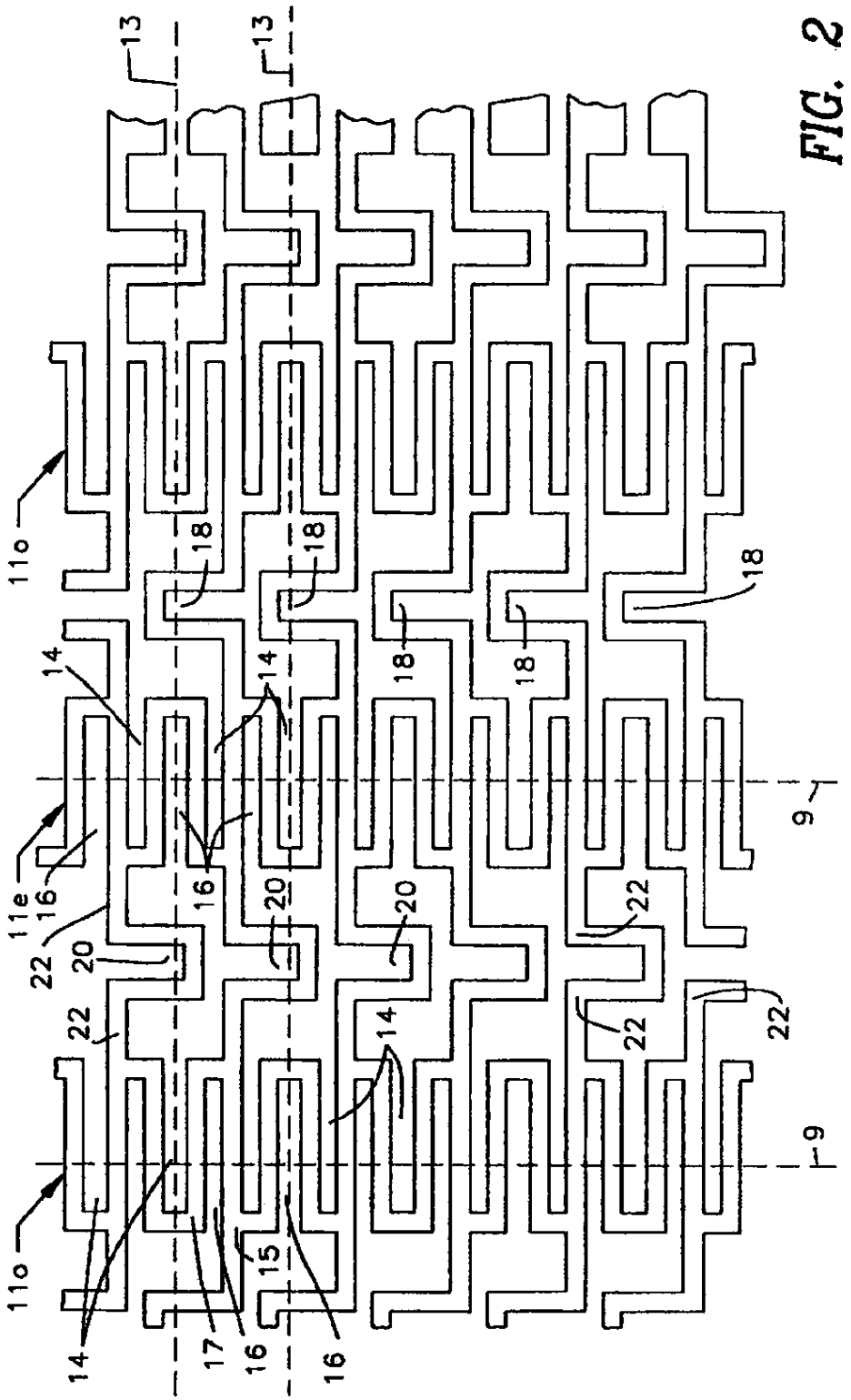

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FIG. 2

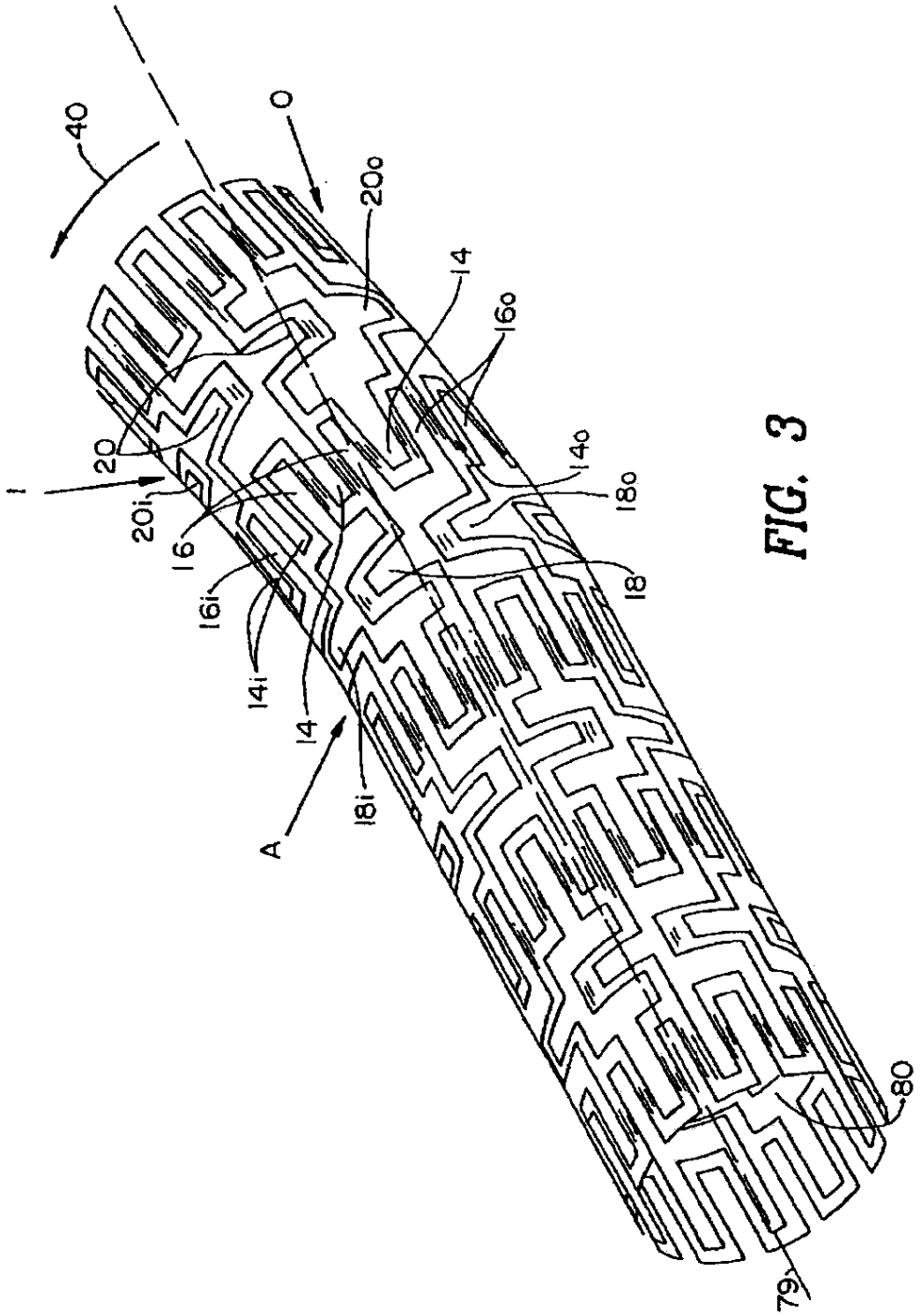

FIG. 3

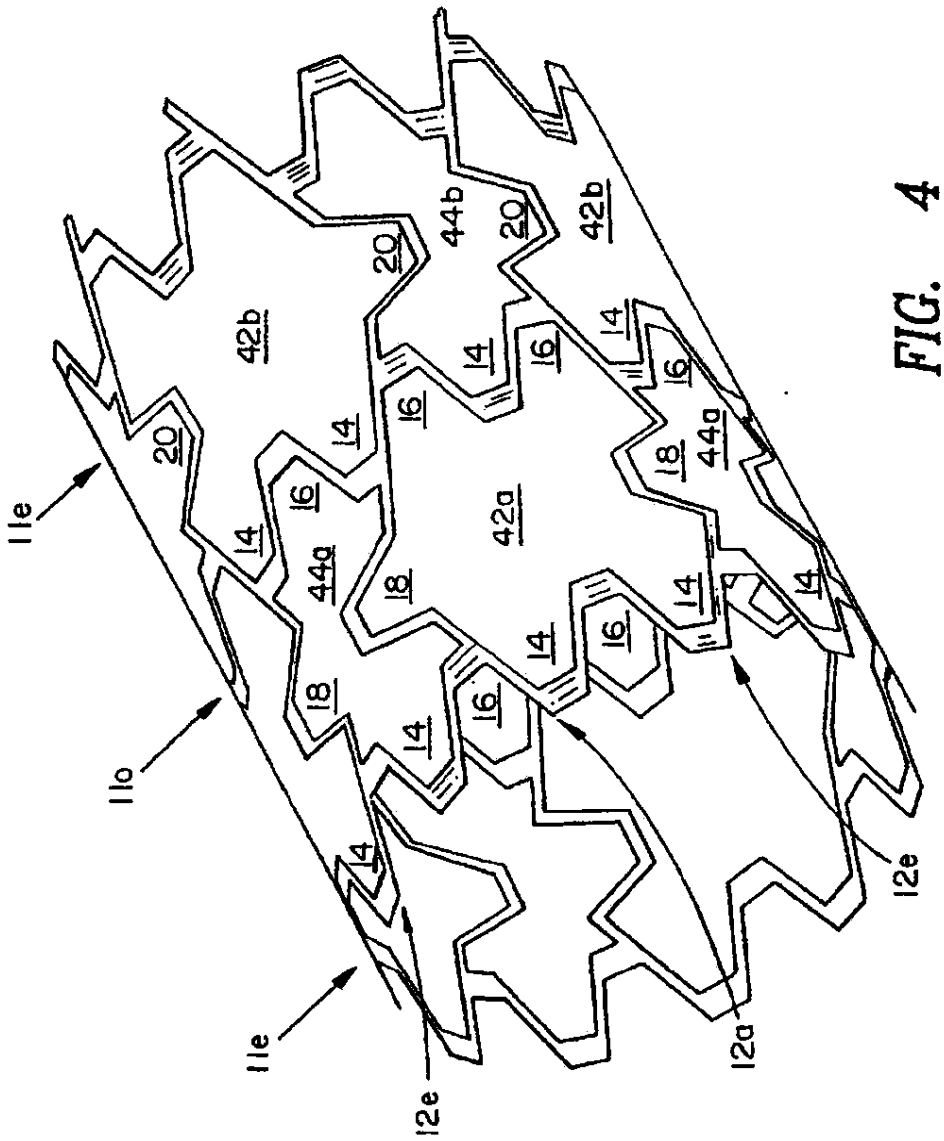

FIG. 4

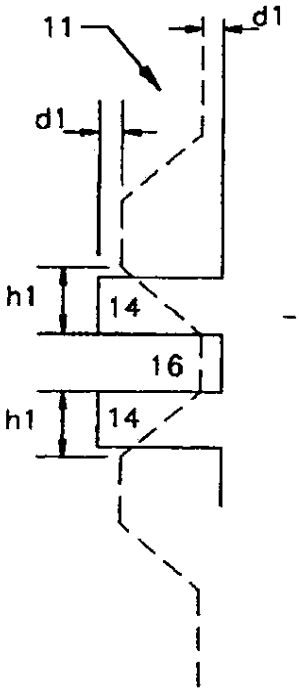

FIG. 5A

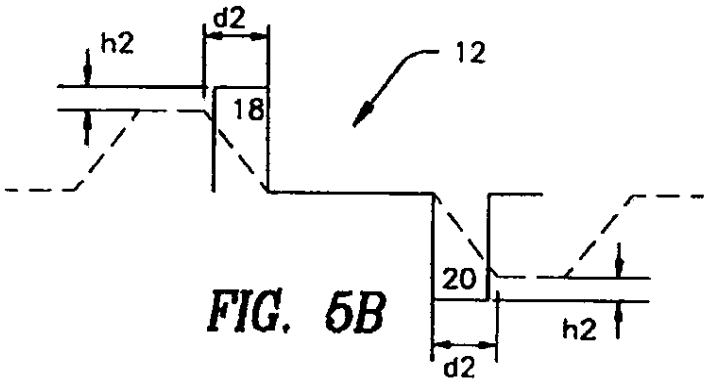

FIG. 5B

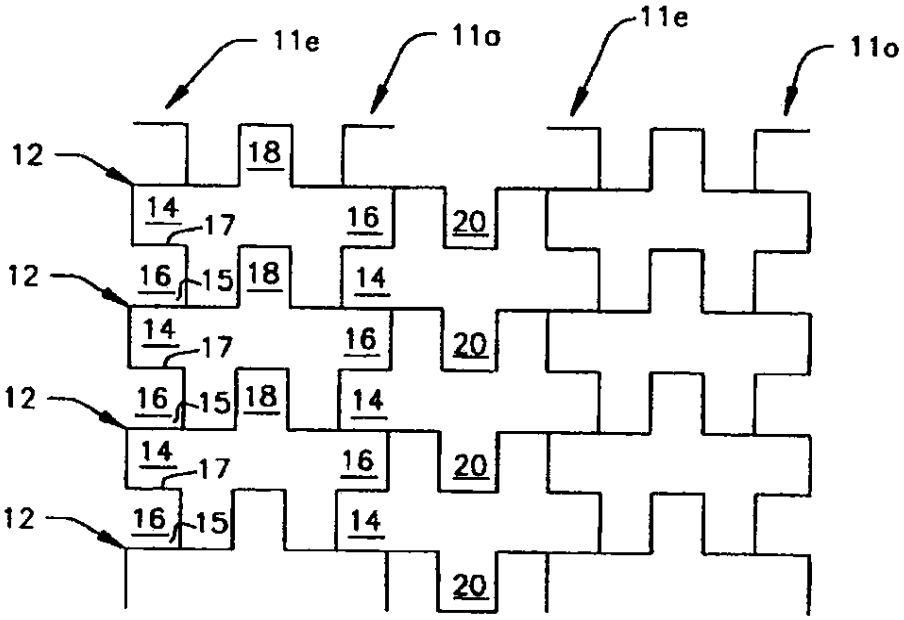

FIG. 6

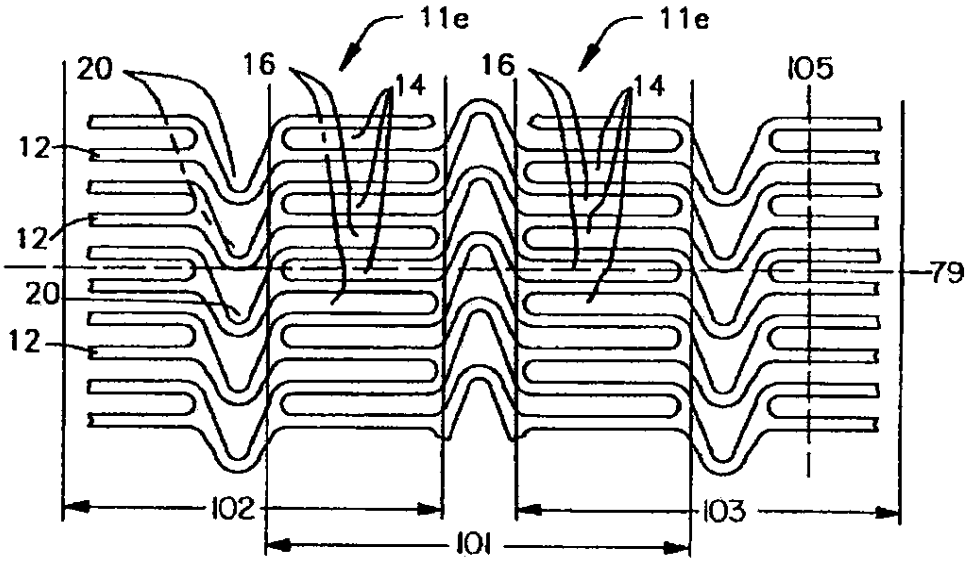
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FIG. 7

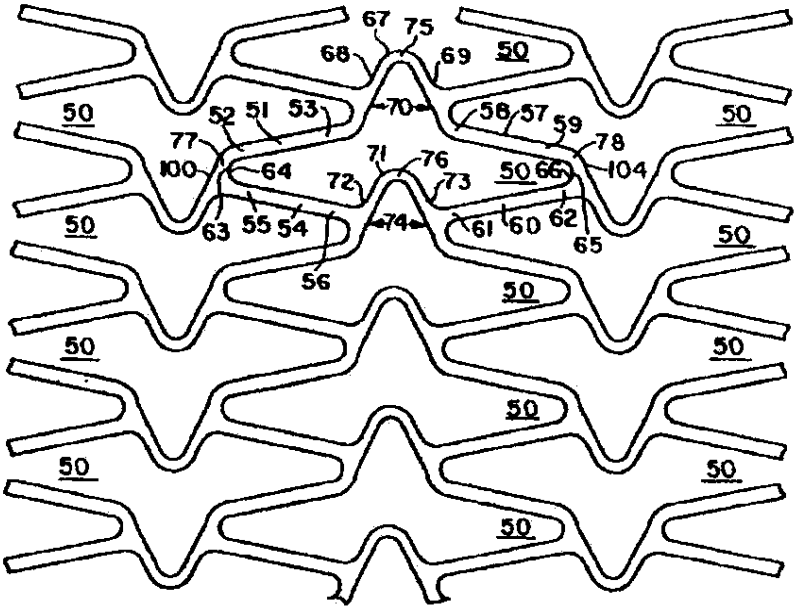
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FIG. 8

FLEXIBLE EXPANDABLE STENT

This application is a continuation of application Ser. No. 08/282,181, filed Jul. 28, 1994, and now abandoned, and 08/213,272 filed Mar. 17, 1994, now U.S. Pat. No. 5,449,373.

FIELD OF THE INVENTION

The present invention relates generally to stents for implanting into a living body.

BACKGROUND OF THE INVENTION

Various stems are known in the an wherein, for the present application, the term "stent" indicates a device, made of body-compatible material, which is utilized to widen a blood vessel, or other orifice in the body, and to maintain the resultant size of the lumen. Typically, the stent is delivered to the desired location in the body with an inflatable balloon and, when the balloon is inflated, the stem expands, thereby widening the orifice. Other mechanical devices which cause expansion of the stent are also utilized.

Exemplary patents in the field of stents formed of wire are: U.S. Pat. No. 5,019,090 to Pinchuk, U.S. Pat. No. 5,161,547 to Tower, U.S. Pat. No. 4,950,227 to Savin, et al., U.S. Pat. No. 5,314,472 to Fontaine, U.S. Pat No. 4,886,062 and U.S. Pat. No. 4,969,458 to Wiktor and U.S. Pat. No. 4,856,516 to Hillstead. Stems formed of cut stock metal are described in: U.S. Pat. No. 4,733,665 to Palmaz, U.S. Pat. No. 4,762,128 to Rosenbluth, U.S. Pat. No. 5,102,417 to Palmaz and Schatz, U.S. Pat. No. 5,195,984 to Schatz and WO 91FR013820 to Meadox.

The stems described in U.S. Pat. No. 5,102,417 to Palmaz and Schatz have expandable tubular grafts connected together with a flexible connector. The grafts are formed of a plurality of slots disposed parallel to the longitudinal axis of the tube. The flexible connectors are helical connectors. Since the tubular grafts are relatively rigid, the flexible connectors are needed so that the stents can bend when being fed through a curved blood vessel. When the stents of U.S. Pat. No. 5,102,417 expand, the grafts expand radially and, consequently, shrink longitudinally. However, at the same time, the helical connectors twist. The twisting motion is most probably harmful to the blood vessel.

U.S. Pat. No. 5,195,984 to Schatz describes a similar stent but with one straight connector, parallel to the longitudinal axis of the tubular grafts, between tubular grafts. The straight member removes the twisting motion; however, it is not a very strong connector.

SUMMARY OF THE PRESENT INVENTION

It is therefore an object of the present inveation to provide a flexible stent which minimally shrinks, in the longitudinal direction, during expansion.

The stent of the present invention is formed of a tube having a patterned shape which has first and second meander patterns having axes extending in first and second directions wherein the second meander patterns are intertwined with the first meander patterns. The first and second directions can be orthogonal to each other.

In accordance with one embodiment of the present invention, the first meander patterns are formed into even and odd first meander patterns. The even and odd first meander patterns are 180° out of phase with each other and the odd patterns occur between every two even patterns. The second meander patterns can also be formed of even and odd patterns.

Additionally, in accordance with a preferred embodiment of the present invention, the second meander patterns have two loops per period and the even and odd first meander patterns are connected on first and second sides, respectively, of each loop of the second meander patterns.

Alternatively or in addition, the second meander patterns are formed of even and odd second meander patterns. In this embodiment, the even and odd first meander patterns have loops and the even and odd second meander patterns are connected to the even and odd first meander patterns so as to leave one full loop between each pair of even and odd second meander patterns.

Moreover, in accordance with a preferred embodiment of the present invention, the first and second meander patterns are formed from flat metal. Alternatively, they can be cut from wire. Further, they can be imbedded or covered with any body-compatible material.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be understood and appreciated more fully from the following detailed description taken in conjunction with the drawings in which:

FIG. 1 is an illustration of a patterned stent, constructed and operative in accordance with a first preferred embodiment of the present invention;

FIG. 2 is an illustration of the pattern of the stent of FIG. 1;

FIG. 3 is an illustration of the stent of FIG. 1 in a bent position;

FIG. 4 is an illustration of the stent of FIG. 1 in an expanded format;

FIGS. 5A and 5B are illustrations of the changes in the patterns of the stent of FIG. 1 due to expansion;

FIG. 6 is a schematic illustration of a second embodiment of the pattern for a steat;

FIG. 7 is an illustration of a third embodiment of the pattern for the stent; and

FIG. 8 is an illustration of the pattern of FIG. 7 in an expanded format.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Reference is now made to FIGS. 1–4 which illustrate a first embodiment of a stent, constructed and operative in accordance with the principles of the present invention. FIG. 1 illustrates the stent in its non-expanded form. FIG. 2 illustrates the pattern of the stent. FIG. 3 illustrates it in a partially bent position and FIG. 4 illustrates it in an expanded form. As shown in FIG. 3, the stent 30 defines a longitudinal aperture 80 having a longitudinal axis or longitudinal extension 79.

The stent of the present invention is a tube whose sides are formed into a plurality of each of two orthogonal meander patterns which patterns are intertwined with each other. The term "meander pattern" is taken herein to describe a periodic pattern about center line and "orthogonal meander patterns" are patterns whose center lines are orthogonal to each other.

In the stent of FIGS. 1–4, the two meander patterns are labeled 11 and 12 and they are most easily seen in FIG. 2. Meander pattern 11 is a vertical sinusoid having a vertical center line 9. Meander pattern 11 has two loops 14 and 16 per period wherein loops 14 open to the right while loops 16 open to the left. Loops 14 and 16 share common members 15 and 17, where member 15 connects from one loop 14 to

its following loop **16** and member **15** connects from one loop **16** to its following loop **14**.

Meander pattern **12** is an horizontal pattern having an horizontal center line **13**. Meander pattern **12** also has loops, labeled **18** and **20**, but between loops of a period is an extended straight section labeled **22**. Loops **18** open downwards and loops **20** open upwards.

Vertical meander pattern **11** is provided in odd and even (o and e) versions which are 180° out of phase with each other. Thus, each left opening loop **16** of meander pattern **11***o* faces a right opening loop **14** of meander pattern **11***e* and a right opening loop **14** of meander pattern **11***o* faces a left opening loop **16** of meander pattern **11***e*.

Horizontal meander pattern **12** is also provided in odd and even forms. The straight sections **22** of horizontal meander pattern **12***e* intersect with every third common member **17** of vertical meander pattern **11***e*. The straight sections **22** of horizontal meander pattern **12***o* intersect with every third common member **15** of vertical meander pattern **11***e*, beginning with the common member **15** two after an intersected common member **17**. The result is a full loop **14** between meander patterns **12***e* and **12***o* and a full loop **16** between meander patterns **12***o* and **12***e*.

Returning to FIG. **1**, the pattern of FIG. **2** is formed into a tube **30** of an easily deformable material, such as a metal. Due to the two meander patterns, the stent of FIG. **1**, when attached over a catheter balloon, is flexible and can therefore be easily dragged through curved blood vessels. An example of the way in which the stent of FIG. **1** bends is illustrated in FIG. **3**.

In FIG. **3**, the stent begins to bend at the point marked A in the direction marked by arrow **40**. As the stent begins to curve, the section marked I becomes the inside of the curve while the section marked O becomes the outside of the curve. The inside of the curve I is shortened vis-a-vis the outside of the curve O.

During bending, the loops **14–20** to the right of the point A change shape in order to compensate for the differences in length between the inside and outside curves. For example, loops **18***i* and **20***i* near the inside of the curve are closer together than loops **18***o* and **20***o* on the outside of the curve, which expand. Loops **14***i* and **16***i* near the inside I are compressed while the loops **14***o* and **16***o* closer to the outside O of the curve are expanded.

As can be seen, both meander patterns **11** and **12** are involved in the bending. Although not shown, it will be appreciated that the stent of FIGS. **1–4** can bend in any direction and in more than one direction at any time.

FIG. **4** illustrates the stent of FIG. **1** in its expanded form. When the stent expands, both meander patterns **11** and **12** expand (i.e. all loops **14–20** open up). As can be seen, the expanded stent has two types of enclosed spaces, a large space **42** between meander patterns **12***o* and **12***e* and a small space **44** between meander patterns **12***e* and **12***o*. As can also be seen, each large space **42** has two loops **14** on its left side and two loops **16** on its right side. The large spaces between vertical meander patterns **11***e* and **11***o*, which are labeled **42***a*, have loops **18** at their tops and bottoms while the large spaces between vertical meander patterns **11***o* and **11***e*, which are labeled **42***b*, have loops **20** at their tops and bottoms. Similarly for small spaces **44***a* and **44***b*.

It is noted that, due to the orthogonal meander patterns **11** and **12**, the stent of FIG. **1** does not significantly shrink during expansion. This is illustrated in detail in FIGS. **5A** and **5B** to which reference is now made. FIG. **5A** illustrates the movement, during expansion, of one vertical meander pattern **11** and FIG. **5B** illustrates the movement, during expansion, of one horizontal meander pattern **12**. The original patterns are shown with solid lines and the expanded patterns are shown with dashed lines.

The vertical meander pattern **11** of FIG. **5A** expands by widening its loops **14** and **16**. As a result, the vertical meander pattern **11** grows vertically by an amount $2*h_1$ per loop. However, it also shrinks horizontally, by an amount $2*d_1$. Similarly, the horizontal meander pattern **12** of FIG. **5B** expands by widening its loops **18** and **20**. As a result, the horizontal meander pattern **12** grows horizontally by an amount $2d_1$ per loop. However, it also shrinks vertically, by an amount h_2. Thus, the vertical growth of the vertical meander pattern **11** compensates, at least partially, for the vertical shrinkage of the horizontal meander pattern **12**, and vice versa. It is noted that the end portions of any stent are only partially compensated and therefore, may shrink somewhat.

It will be appreciated that the two orthogonal meander patterns **11** and **12** and the compensation they provide to each other provides flexibility to the unexpanded stent of FIG. **1**. However, when the stent is expanded, the changes in each of loops **14** and **16** provide rigidity to the resultant stent and thus, enable the stent to maintain a blood vessel at a desired inner diameter.

The stent of the present invention can be manufactured from flat metal which is etched into the pattern of FIG. **2**. The etched metal is then bent to form the tube **30**. Alternatively, the pattern of FIG. **2** can be manufactured from welded or twisted wire.

It will be appreciated that the stent of the present invention can be made from metal and/or wire. Additionally, it can be plated with a protective material, embedded with a medicine, and/or covered with a material which can fill in the spaces **42** and **44**.

It will be appreciated that the present invention encompasses all stents manufactured with a pattern formed of two meander patterns, orthogonal or otherwise. Another exemplary pattern, also with orthogonal meander patterns, is provided herein wherein FIG. **6** is a schematic version and FIG. **7** is a more rounded version. FIG. **8** shows the pattern of FIG. **7** in an expanded format. The pattern of FIGS. **6** and **7** is similar to that shown in FIG. **2** except that it has more horizontal meander patterns **12** and they are of one kind, rather than being even and odd as in FIG. **2**.

As can be seen in both FIGS. **6** and **7**, there are two types of vertical meander patterns **11***e* and **11***o* which are 180° out of phase with each other. The horizontal meander patterns **12** connect with every line **15** of vertical meander pattern **11***e*.

FIG. **8** illustrates the pattern of FIG. **7** in an expanded format. Since there are no even and odd horizontal meander patterns, in the expanded format of FIG. **8**, there are no large and small spaces. Instead, all spaces are of the same size, i.e. the stent is comprised of a plurality of spaces or cells **50** defining a uniform cellular structure.

As shown in FIGS. **3**, **7** and **8**, Applicants' invention can also be described as an expandable stent defining a longitudinal aperture **80** having a longitudinal axis or extension **79** and a circumferential axis or extension **105**, including a plurality of flexible connected cells **50** with each of the flexible cells **50** having a first longitudinal end **77** and a second longitudinal end **78**. Each cell **50** also is provided with a first longitudinal apex **100** disposed at the first longitudinal end **77** and a second longitudinal apex **104** disposed at the second longitudinal end **78**. Each cell **50** also includes a first member **51** having a longitudinal component

having a first end 52 and a second end 53; a second member 54 having a longitudinal component having a first end 55 and a second end 56; a third member 57 having a longitudinal component having a first end 58 and a second end 59; and a fourth member 60 having a longitudinal component having a first end 61 and a second end 62. The stent also includes a first loop 63 defining a first angle 64 disposed between the first end 52 of the first member 51 and the first end 55 of the second member 54. A second loop 65 defining a second angle 66 is disposed between the second end 59 of the third member 57 and the second end 62 of the fourth member 60 and is disposed generally opposite to the first loop 63. A first flexible compensating member or flexible link 67 having a first end 68 and a second end 69 is disposed between the first member 51 and the third member 57 with the first end 68 of the first flexible compensating member or flexible link 67 communicating with the second end 53 of the first member 51 and the second end 69 of the first flexible compensating member or flexible link 67 communicating with the first end 58 of the third member 57. The first end 68 and the second end 69 are disposed a variable longitudinal distance 70 from each other. A second flexible compensating member 71 having a first end 72 and a second end 73 is disposed between the second member 54 and the fourth member 60. The first end 72 of the second flexible compensating member or flexible link 71 communicates with the second end 56 of the second member 54 and the second end 73 of the second flexible compensating member or flexible link 71 communicates with the first end 61 of the fourth member 60. The first end 72 and the second end 73 are disposed a variable longitudinal distance 74 from each other. In a preferred embodiment, the first and second flexible compensating member or flexible links 67 and 71 are arcuate. The first and second flexible compensating member or flexible links 67 and 71 are differentially extendable or compressible when the stent is bent in a curved direction away from the longitudinal axis 79 of the aperture 80. (Shown in FIG. 3.) The first member 51, second member 54, third member 57, and fourth member 60 and the first loop 63 and the second loop 65 and the first flexible compensating member or flexible link 67 and the second flexible compensating member or flexible link 71 are disposed so that as the stent is expanded the distance between the first flexible compensating member or flexible link 67 and the second flexible compensating member or flexible link 71 increases and the longitudinal component of the first member 51, second member 54, third member 57 and fourth member 60 decreases while the first loop 63 and the second loop 65 remain generally opposite to one another, the ends 68 and 69 of the first flexible compensating member or flexible link 67 and the ends 72 and 73 of the second flexible compensating member or flexible link 71 open so as to increase the variable longitudinal distance 70 between the first end 68 and the second end 69 of the first flexible compensating member or flexible link 67 and so as to increase the variable longitudinal distance 74 between the first end 72 and the second end 73 of the second flexible compensating member or flexible link 71. This compensates for the decreasing of the longitudinal component of the first member 51, second member 54, third member 57, and fourth member 60 and substantially lessens the foreshortening of the stent upon its expansion. In a preferred embodiment, and as shown in FIG. 5A, the flexible compensating member or flexible links 67 and 71 compensate in an amount that is substantially equal to the amount that the stent foreshortens. As shown in FIGS. 7 and 8, the first flexible compensating member or flexible link 67 and the second flexible compensating member or flexible link 71 in each cell 50 of each row or band of cells 101, 102 and 103, serve to flexibly connect other cells 50 in adjacent rows or bands 102, 103, and 104 which themselves have first and second compensating members 67 and 71. As shown in FIG. 7, the first flexible compensating member or flexible links 67 and 71 in row or band 101 serve to flexibly connect the cells 50 in adjacent rows or bands 102 and 103. As shown in FIGS. 7 and 8, a portion of the flexible member 67 or 71 disposed between the first ends 68 and 72 and the second ends 69 and 73 may be provided with a width that is smaller than the width of the apices 100 and 104 to which they are attached.

It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Rather the scope of the present invention is defined by the claims which follow:

We claim:

1. A stent formed of a tube having a patterned shape, the patterned shape comprising:

even first meander patterns having axes extending in a first direction;

odd first meander patterns, also having axes extending in said first direction, wherein said odd first meander patterns are 180° out of phase with said even first meander patterns and occur between every two even first meander patterns;

second meander patterns having axes extending in a second direction, wherein said second meander patterns are intertwined with said even and odd first meander patterns to form a distributed structure,

wherein said second meander patterns have two loops per period and

wherein said even and odd first meander patterns are connected on first and second sides, respectively, of each loop.

2. The stent of claim 1, wherein said second meander patterns define a plurality of flexible arcuate compensating members adapted to elongate in said second direction to compensate for the tendency of said first meander patterns to foreshorten when said stent is expanded.

3. A stent formed of a tube having a patterned shape, the patterned shape comprising:

even first meander patterns having axes extending in a first direction;

odd first meander patterns, also having axes extending in said first direction, wherein said odd first meander patterns are 180° out of phase with said even first meander patterns and occur between every two even first meander patterns;

second meander patterns having axes extending in a second direction, wherein said second meander patterns are intertwined with said even and odd first meander patterns to form a distributed structure, and

wherein said second meander patterns are formed of even and odd second meander patterns.

4. A stent according to claim 3 and wherein said even and odd first meander patterns have loops and wherein said even and odd second meander patterns are connected to said even and odd first meander patterns so as to leave one full loop between each pair of even and odd second meander patterns.

5. The stent of claim 3, wherein said second meander patterns define a plurality of flexible arcuate compensating members adapted to elongate in said second direction to compensate for the tendency of said first meander patterns to foreshorten when said stent is expanded.

6. An expandable stent defining a longitudinal aperture, including:

a plurality of flexible connected cells, each of said flexible cells comprising:

a) a first member having a longitudinal component having a first end and a second end;

b) a second member having a longitudinal component having a first end and a second end,

c) a third member having a longitudinal component having a first end and a second end;

d) a fourth member having a longitudinal component having a first end and a second end;

e) a first loop defining a first angle disposed between said first end of said first member and said first end of said second member;

f) a second loop defining a second angle disposed between said second end of said third member and said second end of said fourth member, and disposed generally opposite to said first loop;

g) a first flexible compensating member or flexible link having a first end and a second end disposed between said first member and said third member, said first end of said first flexible compensating member or flexible link communicating with said second end of said first member and said second end of said first flexible compensating member or flexible link communicating with said first end of said third member, said first and said second ends disposed a variable longitudinal distance from each other;

h) a second flexible compensating member or flexible link having a first end and a second end disposed between said second member and said fourth member, said first end of said second flexible compensating member or flexible link communicating with said second end of said second member and said second end of said second flexible compensating member or flexible link communicating with said first end of said fourth member, said first and said second ends disposed a variable longitudinal distance from each other, said first and said second flexible compensating member or flexible links differentially extendable or compressible when said stent is bent in a curved direction away from the longitudinal axis of said aperture; and

i) said first, said second, said third, and said fourth members and said first and said second loops, and said first and said second flexible compensating member or flexible links disposed so that as said stent is expanded the distance between said first and said second flexible compensating member or flexible links increases and the longitudinal component of said first, second, third and fourth members decreases while said first and said second loops remain generally opposite to one another, the ends of said first and said second flexible compensating member or flexible links open so as to increase said variable longitudinal distance between said first and said second ends of said first flexible compensating member or flexible link and so as to increase said variable longitudinal distance between said first and said second ends of said second flexible compensating member or flexible link so as to compensate for the decreasing of the longitudinal component of said first, second, third, and fourth members and substantially lessen the foreshortening of said stent upon its expansion.

7. The stent of claim 6, wherein the material of said first and said second compensating members is provided with a width that is smaller than the width of the material of said first and said second loops.

8. The stent according to claim 7 wherein said compensating members define an area of inflection between said first end and said second end and said area of inflection remains inflected after the expansion of said stent.

9. The stent of claim 8 in which the area of inflection enlarges during the expansion of the stent.

10. The stent of claim 6, in which said members are generally straight.

11. The stent of claim 6, wherein said first flexible compensating member or flexible link is arcuate and said second flexible compensating member or flexible link is arcuate and said compensating members elongate in an amount substantially equal to the amount that the distance between the ends of said first and second members and said third and fourth members increases when said stent is expanded.

12. The stent of claim 6, wherein said cells define a uniform cellular structure.

13. The stent of claim 6, wherein said first flexible compensating member or flexible link and said second flexible compensating member or flexible link also serve to connect other cells which themselves have first and second compensating members.

14. The stent of claim 6, wherein said first and said second flexible compensating member or flexible links do not tend to project into or outside of said longitudinal aperture when said stent is expanded.

15. The stent of claim 6, wherein said first and said second flexible compensating member or flexible links do not tend to project into or outside of said longitudinal aperture when said stent is flexed.

16. An expandable stent having a longitudinal axis, which consists essentially of:

a plurality of flexible cells having a longitudinal axis and a first longitudinal and a second longitudinal end, said cells disposed about the circumference of the stent, each of said cells comprising:

a first pair of members connected by an area of inflection generally disposed at said first longitudinal end of said cell;

a second pair of members connected by an area of inflection generally disposed at said second longitudinal end of said cell; and

a plurality of flexible links connecting said first and second pair of members and generally disposed between each neighboring cell about the circumference of said stent, wherein said flexible links have some area with a width smaller than the width of said areas of inflection.

17. An expandable stent, including:

a plurality of connected cells defining a substantially uniform structure defining a longitudinal aperture having a longitudinal axis, said cells arranged in a plurality of bands, each of said bands lying in a plane substantially perpendicular to said longitudinal axis, each of said plurality of cells in each of said bands comprising:

a) a first member having a first end and a second end;

b) a second member having a first end and a second end,

c) a third member having a first end and a second end;

d) a fourth member having a first end and a second end;

e) a first loop defining a first angle disposed between said first end of said first member and said first end of said second member;

f) a second loop defining a second angle disposed between said second end of said third member and said second end of said fourth member;

g) a first flexible arcuate compensating member disposed between said second end of said first member and said first end of said third member;

h) a second flexible arcuate compensating member disposed between said second end of said second member and said first end of said fourth member, said first flexible arcuate compensating member and said second flexible arcuate compensating member of each of said plurality of cells in each of said plurality of bands flexibly connecting adjacent bands.

18. The stent of claim 17 wherein said first and said second flexible arcuate compensating members are adapted to lengthen upon the expansion of said stent to compensate for the tendency of said stent to foreshorten when said stent is expanded.

19. The stent of claim 18 wherein said first and said second flexible arcuate compensating members elongate in an amount substantially equal to the amount that the distance between the ends of said first and second members and said third and fourth members increases when said stent is expanded by a catheter balloon.

20. The stent of claim 17, wherein said first and said second flexible arcuate compensating members are readily differentially compressible or expandable when said stent is unexpanded and are less differentially compressible or expandable after said stent is expanded.

21. The stent of claim 17, wherein said first and said second flexible arcuate compensating members are provided with a width that is smaller than the width of said first, said second, said third, and said fourth members and said first loop and said second loop.

22. A stent formed of a tube having a patterned shape, the patterned shape comprising:

first meander patterns which are periodic about axes extending in a first direction;

second meaner patterns which are periodic about axes extending in a second direction different than said first direction, wherein said second meander patterns are intertwined with said first meander patterns to form a generally uniform distributed structure, wherein said second meander patterns define a plurality of flexible arcuate compensating members adapted to elongate in said second direction to compensate for the tendency of said first meander patterns to foreshorten when said stent is expanded.

23. A generally longitudinally extending tubular stent which is substantially uniformly flexible with respect to its longitudinal axis by the flexibility of its cells with respect to said axis including:

(a) a plurality of cells flexible around said longitudinal axis connected to one another about the circumference of said stent to form a band of flexible cells, each of said flexible cells having apices disposed apart and generally opposite to one another along said longitudinal extension of the cell,

(b) each of said flexible cells having a plurality of flexible links disposed apart and generally opposite to one another along the circumfereatial extension of said cells,

(c) each of said flexible links including a plurality of portions with neighboring portions having an area of inflection therebetween; and

(d) said flexible cells in said adjacent bands of flexible cells connected to one another.

24. A flexible connector for connecting the apices of cells included in a stent, including: a flexible member having a first end and a second end with an area of inflection disposed between said first end and said second end, a portion of said flexible member having a width smaller than the width of said apices to which said first end and said second end are connected.

25. The connector of claim 24, wherein said portion is in said area of inflection.

26. The connector of claim 24, wherein said portion is adjacent to each side of the center of the area of inflection.

27. The connector of claim 24, wherein said portion is disposed between said first end and said second end.

28. An expandable stent, including:

a plurality of connected cells having a longitudinal axis defining a substantially uniform structure of flexible cells having a longitudinal axis and a circumferential axis substantially perpendicular to said longitudinal axis;

each of said flexible cells having apices disposed apart and generally opposite to one another along said longitudinal axis of each of said cells;

each of said flexible cells having at least two flexible links disposed apart and generally opposite to one another about the circumferential extension of the cell, each of said flexible links including at least two portions with an area of inflection therebetween.

29. An expandable stent, consisting essentially of:

a plurality of flexible cells disposed about the circumference of the stent, each of said cells having a first longitudinal end and a second longitudinal end, each of said cells comprising:

a first pair of members connected by an area of inflection generally disposed at said first longitudinal end of each of said cells;

a second pair of members connected by an area of inflection generally disposed at said second longitudinal end of each of said plurality of cells; and

a flexible link connecting said first and second pair of members and generally disposed about the circumference of the stent between each neighboring cell.

30. An expandable stent having a longitudinal axis, comprising:

a plurality of flexible cells having a longitudinal axis and a first longitudinal and a second longitudinal end, said cells disposed about the circumference of the stent, each of said cells comprising:

a first pair of members connected by an area of inflection generally disposed at said first longitudinal end of said cell;

a second pair of members connected by an area of inflection generally disposed at said second longitudinal end of said cell; and

a plurality of flexible links connecting said first and second pair of members and generally disposed between each neighboring cell about the circumference of said stent.

31. The stent of claim 29 or 30, wherein said flexible links have some area with a width smaller than the width of said areas of inflection.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,733,303 Page 1 of 2

DATED : March 31, 1998

INVENTOR(S) : Israel et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the title page, in the Related U.S. Application Data, line 2, "continuation" should be --continuation-in-part--.

In Figure 4, the reference "12a" should be --12o--.

In Figure 7, the reference "11e" on the left side should be --11o--.

In Figure 8, delete the reference numerals "75" and "76" and their associated lead lines.

In column 1, line 4, insert --a continuation-in-part of application Ser. No.-- before "08/213,272".

In column 1, line 13, "stems" should be --stents--.

In column 1, line 13, "an" should be --art--.

In column 1, line 19, "stem" should be --stent--.

In column 1, line 27, "Stems" should be --Stents--.

In column 1, line 33, "stems" should be --stents--.

In column 2, line 67, "member 15" should be --member 17--.

In column 3, line 52, "all loops 14-20" should be --all loops 14, 16, 18, and 20--.

In column 3, line 57, "fight" and insert --right--.

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,733,303 Page 2 of 2
DATED : March 31, 1998
INVENTOR(S) : Israel et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In column 4, line 12, "2d2" should be --2*d2--.
In column 6, line 3, "102, 103, and 104" should be --102 and 103--.
In claim 6, line 8, "," should be --;--.
In claim 6, line 41, "member" should be --members--.
In claim 6, line 56, "member" should be --members--.

Signed and Sealed this

Thirteenth Day of February, 2001

Attest:

Nicholas P. Godici

NICHOLAS P. GODICI

Attesting Officer

Acting Director of the United States Patent and Trademark Office

EXHIBIT D

REDACTED

EXHIBIT E

US005514154A

United States Patent [19]

Lau et al.

[11] **Patent Number: 5,514,154**

[45] **Date of Patent: May 7, 1996**

[54] **EXPANDABLE STENTS**

[75] Inventors: **Lilip Lau**, Sunnyvale; **William M. Hartigan**, Fremont; **John J. Frantzen**, Copperopolis, all of Calif.

[73] Assignee: **Advanced Cardiovascular Systems, Inc.**, Santa Clara, Calif.

[21] Appl. No.: **281,790**

[22] Filed: **Jul. 28, 1994**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 164,986, Dec. 9, 1993, abandoned, which is a continuation of Ser. No. 783,558, Oct. 28, 1991, abandoned.

[51] **Int. Cl.**[6] **A61M 29/00**

[52] **U.S. Cl.** **606/195**; 606/194; 606/108; 623/13

[58] **Field of Search** 606/191–198, 606/108; 604/93, 96, 97, 280, 282, 283; 623/1, 11, 12

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Primary Examiner—Christopher A. Bennett

Attorney, Agent, or Firm—Fulwider Patton Lee & Utecht

[57] **ABSTRACT**

The invention is directed to an expandable stent for implantation in a body lumen, such as an artery, and a method for making it from a single length of tubing. The stent consists of a plurality of radially expandable cylindrical elements generally aligned on a common axis and interconnected by one or more interconnective elements. The individual radially expandable cylindrical elements consist of ribbon-like material disposed in an undulating pattern. Portions of the expanded stent project outwardly into engagement with the vessel wall to more securely attach the stent.

23 Claims, 4 Drawing Sheets

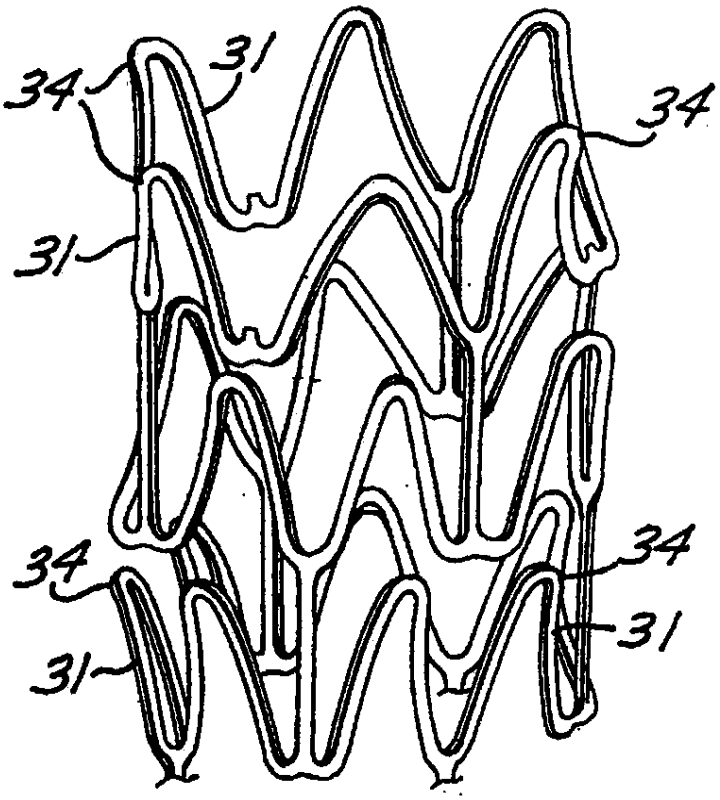


FIG. 1

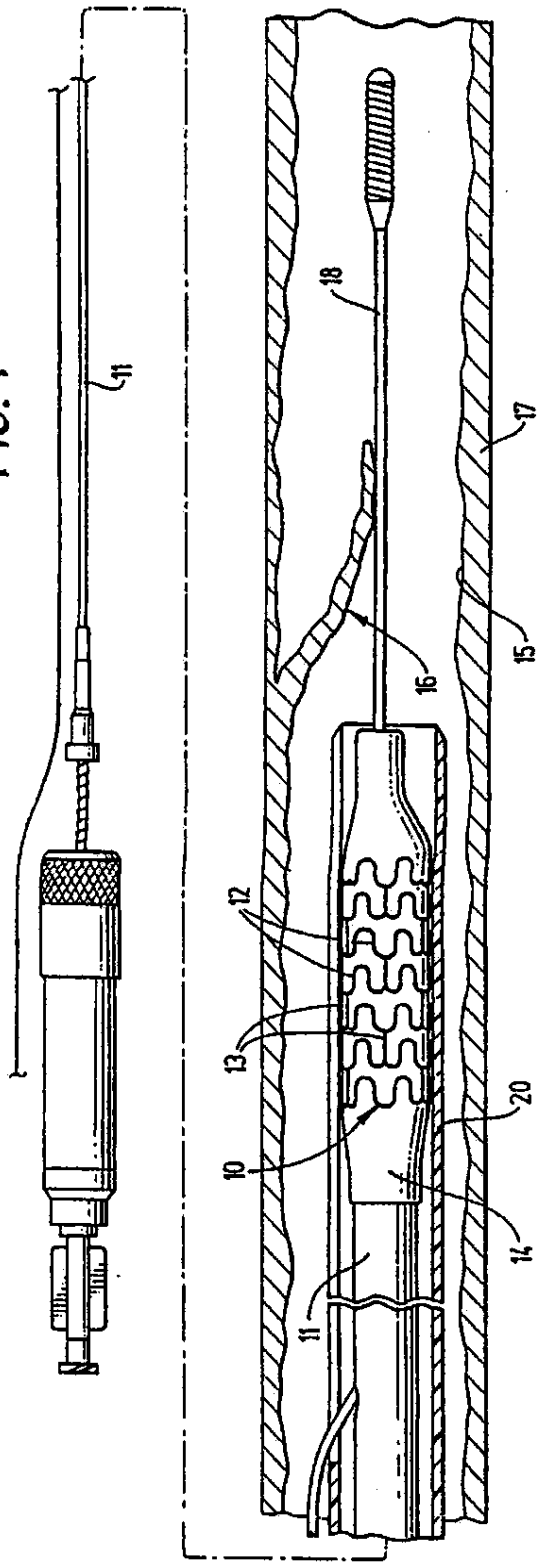


FIG. 3

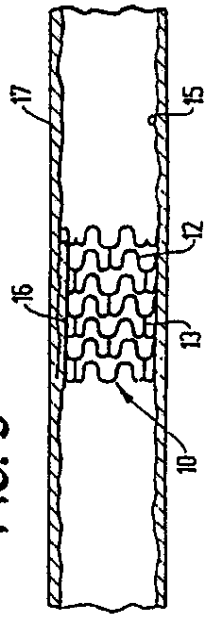


FIG. 2

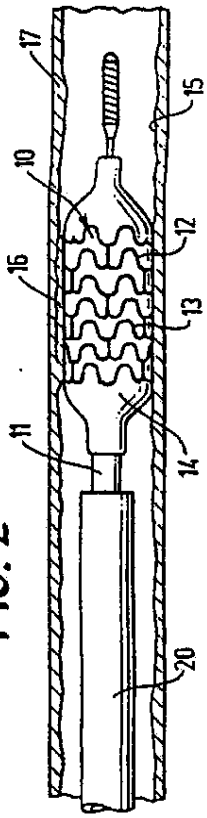


FIG. 4

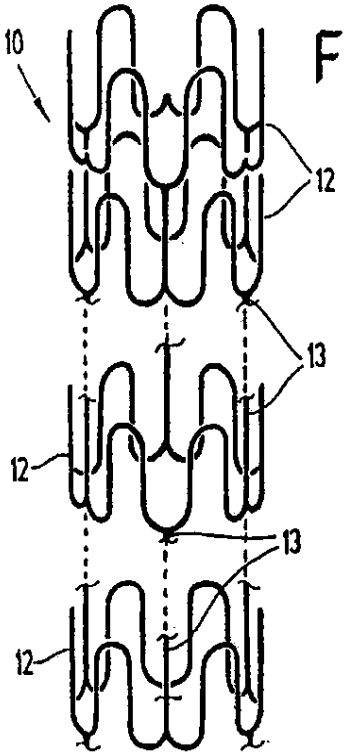


FIG. 6

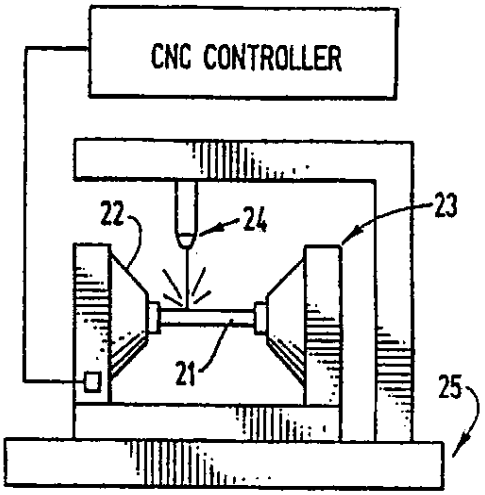


FIG. 5

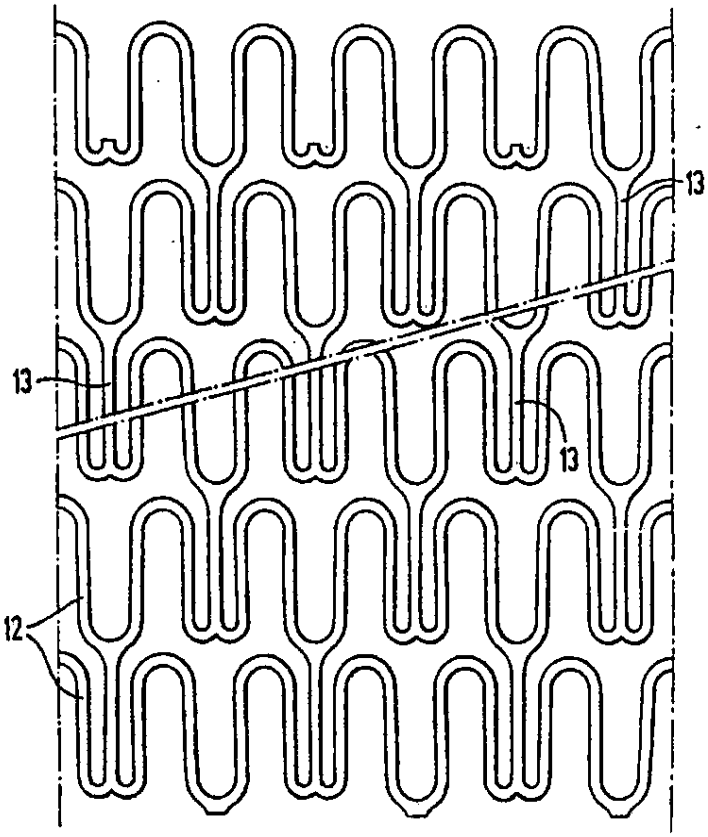


FIG. 7

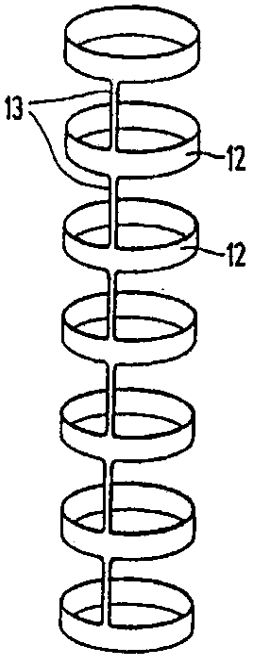


FIG. 8

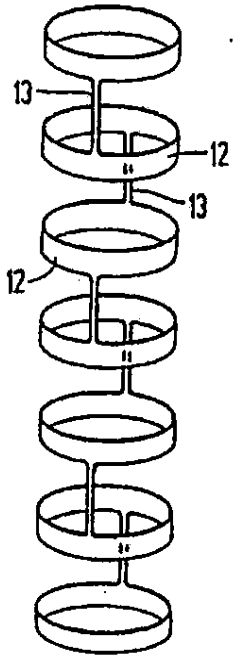


FIG. 9

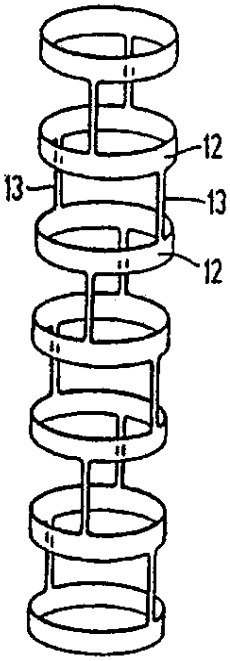


FIG. 10

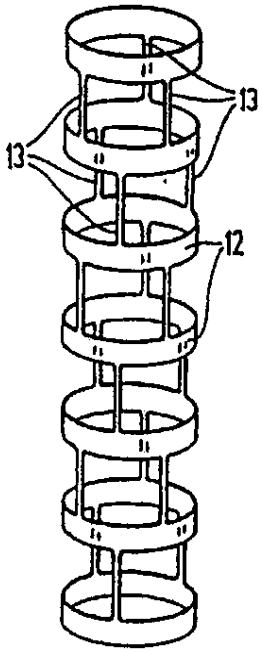
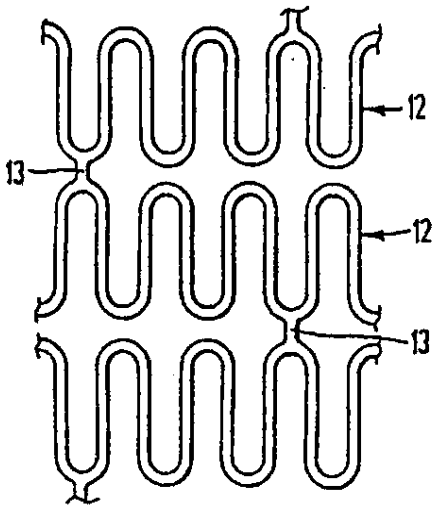


FIG. 11



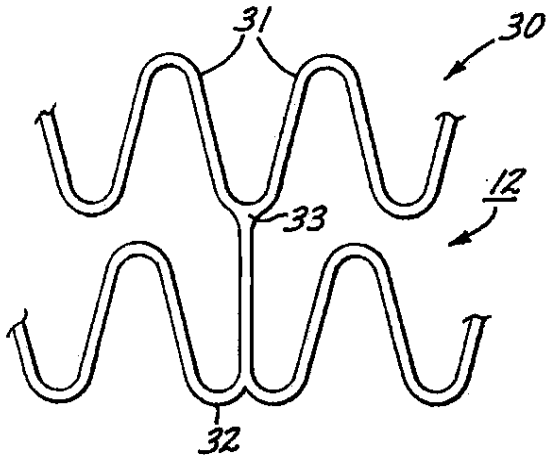


FIG. 12

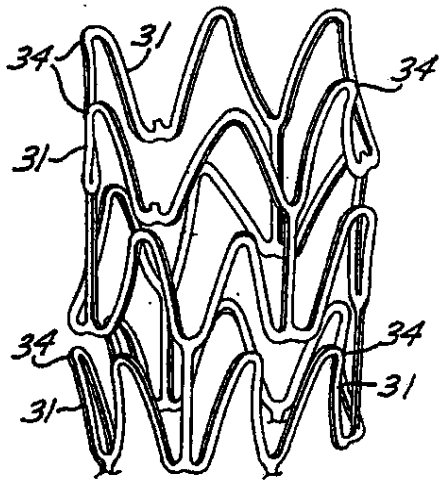


FIG. 13

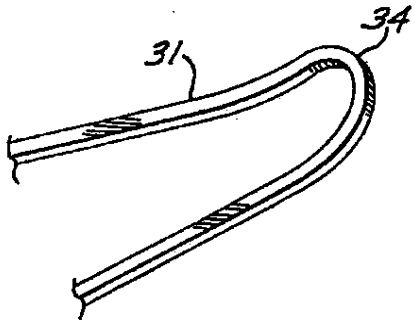


FIG. 14

EXPANDABLE STENTS

RELATED APPLICATIONS

This application is a continuation-in-part of U.S. patent application U.S. Ser. No. 08/164,986 filed Dec. 9, 1993, now abandoned, which is a continuation application of U.S. Ser. No. 07/783,558 filed Oct. 28, 1991, now abandoned.

BACKGROUND OF THE INVENTION

This invention relates to expandable endoprosthesis devices, generally called stents, which are adapted to be implanted into a patient's body lumen, such as blood vessel, to maintain the patency thereof. These devices are very useful in the treatment of atherosclerotic stenosis in blood vessels.

Stents are generally tubular-shaped devices which function to hold open a segment of a blood vessel or other anatomical lumen. They are particularly suitable for use to support and hold back a dissected arterial lining which can occlude the fluid passageway therethrough.

Further details of prior art stents can be found in U.S. Pat. No. 3,868,956 (Alfidi et al.); U.S. Pat. No. 4,512,338 (Balko et al.); U.S. Pat. No. 4,553,545 (Maass et al.); U.S. Pat. No. 4,733,665 (Palmaz); U.S. Pat. No. 4,762,128 (Rosenbluth); U.S. Pat. No. 4,800,882 (Gianturco); U.S. Pat. No. 4,856,516 (Hillstead); and U.S. Pat. No. 4,886,062 (Wiktor), which are hereby incorporated herein in their entirety by reference thereto.

Various means have been described to deliver and implant stents. One method frequently described for delivering a stent to a desired intraluminal location includes mounting the expandable stent on an expandable member, such as a balloon, provided on the distal end of an intravascular catheter, advancing the catheter to the desired location within the patient's body lumen, inflating the balloon on the catheter to expand the stent into a permanent expanded condition and then deflating the balloon and removing the catheter. One of the difficulties encountered using prior stents involved maintaining the radial rigidity needed to hold open a body lumen while at the same time maintaining the longitudinal flexibility of the stent to facilitate its delivery.

What has been needed and heretofore unavailable is a stent which has a high degree of flexibility so that it can be advanced through tortuous passageways and can be readily expanded and yet have the mechanical strength to hold open the body lumen into which it expanded. The present invention satisfies this need.

SUMMARY OF THE INVENTION

The present invention is directed to an expandable stent which is relatively flexible along its longitudinal axis to facilitate delivery through tortuous body lumens, but which is stiff and stable enough radially in an expanded condition to maintain the patency of a body lumen such as an artery when implanted therein.

The stent of the invention generally includes a plurality of radially expandable cylindrical elements which are relatively independent in their ability to expand and to flex relative to one another. The individual radially expandable cylindrical elements of the stent are dimensioned so as to be longitudinally shorter than their own diameters. Interconnecting elements or struts extending between adjacent cylindrical elements provide increased stability and a preferable position to prevent warping of the stent upon the expansion thereof. The resulting stent structure is a series of radially expandable cylindrical elements which are spaced longitudinally close enough so that small dissections in the wall of a body lumen may be pressed back into position against the lumenal wall, but not so close as to compromise the longitudinal flexibilities of the stent. The individual cylindrical elements may rotate slightly relative to adjacent cylindrical elements without significant deformation, cumulatively giving a stent which is flexible along its length and about its longitudinal axis but is still very stiff in the radial direction in order to resist collapse.

The stent embodying features of the invention can be readily delivered to the desired lumenal location by mounting it on an expandable member of a delivery catheter, for example a balloon, and passing the catheter-stent assembly through the body lumen to the implantation site. A variety of means for securing the stent to the expandable member on the catheter for delivery to the desired location are available. It is presently preferred to compress the stent onto the balloon. Other means to secure the stent to the balloon include providing ridges or collars on the inflatable member to restrain lateral movement, or using bioresorbable temporary adhesives.

The presently preferred structure for the expandable cylindrical elements which form the stents of the present invention generally circumferential undulating pattern, e.g. serpentine. The transverse cross-section of the undulating component of the cylindrical element is relatively small and preferably has an apect ratio of about two to one to about 0.5 to one. A one to one aspect ratio has been found particularly suitable. The open reticulated structure of the stent allows for the perfusion of blood over a large portion of the arterial wall which can improve the healing and repair of a damaged arterial lining.

The radial expansion of the expandable cylinder deforms the undulating pattern thereof similar to changes in a waveform which result from decreasing the waveform's amplitude and the frequency. Preferably, the undulating patterns of the individual cylindrical structures are in phase with each other in order to prevent the contraction of the stent along its length when it is expanded. The cylindrical structures of the stent are plastically deformed when expanded (except with NiTi alloys) so that the stent will remain in the expanded condition and, therefore, they must be sufficiently rigid when expanded to prevent the collapse thereof in use. During expansion of the stent, portions of the undulating pattern will tip outwardly resulting in projecting members on the outer surface of the expanded stent. These projecting members tip radially outwardly from the outer surface of the stent and embed in the vessel wall and help secure the expanded stent so that it does not move once it is implanted.

With superelastic NiTi alloys, the expansion occurs when the stress of compression is removed so as to allow the phase transformation from austenite back to martensite and as a result the expansion of the stent.

The elongated elements which interconnect adjacent cylindrical elements should have a transverse cross-section similar to the transverse dimensions of the undulating components of the expandable cylindrical elements. The interconnecting elements may be formed in a unitary structure with the expandable cylindrical elements from the same intermediate product, such as a tubular element, or they may be formed independently and connected by suitable means, such as by welding or by mechanically securing the ends of the interconnecting elements to the ends of the expandable cylindrical elements. Preferably, all of the interconnecting

elements of a stent are joined at either the peaks or the valleys of the undulating structure of the cylindrical elements which for the stent. In this manner there is no shortening of the stent upon expansion.

The number and location of elements interconnecting adjacent cylindrical elements can be varied in order to develop the desired longitudinal flexibility in the stent structure both in the unexpanded as well as the expanded condition. These properties are important to minimize alteration of the natural physiology of the body lumen into which the stent is implanted and to maintain the compliance of the body lumen which is internally supported by the stent. Generally, the greater the longitudinal flexibility of the stent, the easier and the more safely it can be delivered to the implantation site.

In a presently preferred embodiment of the invention the stent is conveniently and easily formed by coating stainless steel tubing with a material resistant to chemical etching, removing portions of the coating to expose portions of underlying tubing which are to be removed to develop the desired stent structure. The exposed portions of the tubing are removed by chemically etching from the tubing exterior leaving the coated portion of the tubing material in the desired pattern of the stent structure. The etching process develops smooth openings in the tubing wall without burrs or other artifacts which are characteristic of mechanical or laser machining processes in the small sized products contemplated. Moreover, a computer controlled laser patterning process to remove the chemical resistive coating makes photolithography technology adaptable to the manufacture of these small products. The forming of a mask in the extremely small sizes needed to make the small stents of the invention would be a most difficult task. A plurality of stents can be formed from one length of tubing by repeating the stent pattern and providing small webs or tabs to interconnect the stents. After the etching process, the stents can be separated by severing the small webs or tabs which connect them.

Other features and advantages of the present invention will become more apparent from the following detailed description of the invention. When taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an elevational view, partially in section, of a stent embodying features of the invention which is mounted on a delivery catheter and disposed within a damaged artery.

FIG. **2** is an elevational view, partially in section, similar to that shown in FIG. **1** wherein the stent is expanded within a damaged artery, pressing the damaged lining against the arterial wall.

FIG. **3** is an elevational view, partially in section showing the expanded stent within the artery after withdrawal of the delivery catheter.

FIG. **4** is a perspective view of a stent embodying features of the invention in an unexpanded state, with one end of the stent being shown in an exploded view illustrate the details thereof.

FIG. **5** is a plan view of a flattened section of a stent of the invention which illustrates the undulating pattern of the stent shown in FIG. **4**.

FIG. **6** is a schematic representation of equipment for selectively removing coating applied to tubing in the manufacturing of the stents of the present invention.

FIGS. **7** through **10** are perspective views schematically illustrating various configurations of interconnective element placement between the radially expandable cylindrical elements of the stent.

FIG. **11** is a plan view of a flattened section of a stent illustrating an alternate undulating pattern in the expandable cylindrical elements of the stent which are out of phase.

FIG. **12** is an enlarged partial view of the stent of FIG. **5** with the various members slightly expanded.

FIG. **13** is a perspective view of the stent of FIG. **4** after it is fully expanded depicting some members projecting radially outwardly.

FIG. **14** is an enlarged, partial perspective view of one U-shaped member with its tip projecting outwardly after expansion.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. **1** illustrates a stent **10** incorporating features of the invention which is mounted onto a delivery catheter **11**. The stent generally comprises a plurality of radially expandable cylindrical elements **12** disposed generally coaxially and interconnected by elements **13** disposed between adjacent cylindrical elements. The delivery catheter **11** has an expandable portion or balloon **14** for expanding of the stent **10** within an artery **15**. The artery **15**, as shown in FIG. **1**, has a dissected lining **16** which has occluded a portion of the arterial passageway.

The delivery catheter **11** onto which the stent **10** is mounted, is essentially the same as a conventional balloon dilatation catheter for angioplasty procedures. The balloon **14** may be formed of suitable materials such as polyethylene, polyethylene terephthalate, polyvinyl chloride, nylon and ionomers such as Surlyn® manufactured by the Polymer Products Division of the Du Pont Company. Other polymers may also be used. In order for the stent **10** to remain in place on the balloon **14** during delivery to the site of the damage within the artery **15**, the stent **10** is compressed onto the balloon. A retractable protective delivery sleeve **20** as described in co-pending applications Ser. No. 07/647,464 filed on Apr. 25, 1990 and entitled STENT DELIVERY SYSTEM may be provided to further ensure that the stent stays in place on the expandable portion of the delivery catheter **11** and prevent abrasion of the body lumen by the open surface of the stent **20** during delivery to the desired arterial location. Other means for securing the stent **10** onto the balloon **14** may also be used, such as providing collars or ridges on the ends of the working portion, i.e. the cylindrical portion, of the balloon.

Each radially expandable cylindrical element **12** of the stent **10** may be independently expanded. Therefore, the balloon **14** may be provided with an inflated shape other than cylindrical, e.g. tapered, to facilitate implantation of the stent **10** in a variety of body lumen shapes.

In a preferred embodiment, the delivery of the stent **10** is accomplished in the following manner. The stent **10** is first mounted onto the inflatable balloon. **14** on the distal extremity of the delivery catheter **11**. The balloon **14** is slightly inflated to secure the stent **10** onto the exterior of the balloon. The catheter-stent assembly is introduced within the patient's vasculature in a conventional Seldinger technique through a guiding catheter (not shown). A guidewire **18** is disposed across the damaged arterial section with the detached or dissected lining **16** and then the catheter-stent assembly is advanced over a guidewire **18** within the artery

15 until the stent 10 is directly under the detached lining 16. The balloon 14 of the catheter is expanded, expanding the stent 10 against the artery 15, which is illustrated in FIG. 2. While not shown in the drawing, the artery 15 is preferably expanded slightly by the expansion of the stent 10 to seat or otherwise fix the stent 10 to prevent movement. In some circumstances during the treatment of stenotic portions of an artery, the artery may have to be expanded considerably in order to facilitate passage of blood or other fluid therethrough.

The stent 10 serves to hold open the artery 15 after the catheter 11 is withdrawn, as illustrated by FIG. 3. Due to the formation of the stent 10 from elongated tubular member, the undulating component of the cylindrical elements of the stent 10 is relatively flat in transverse cross-section, so that when the stent is expanded, the cylindrical elements are pressed into the wall of the artery 15 and as a result do not interfere with the blood flow through the artery 15. The cylindrical elements 12 of stent 10 which are pressed into the wall of the artery 15 will eventually be covered with endothelial cell growth which further minimizes blood flow interference. The undulating portion of the cylindrical sections 12 provide good tacking characteristics to prevent stent movement within the artery. Furthermore, the closely spaced cylindrical elements 12 at regular intervals provide uniform support for the wall of the artery 15, and consequently are well adapted to tack up and hold in place small flaps or dissections in the wall of the artery 15 as illustrated in FIGS. 2 and 3.

FIG. 4 is an enlarged perspective view of the stent 10 shown in FIG. 1 with one end of the stent shown in an exploded view to illustrate in greater detail the placement of interconnecting elements 13 between adjacent radially expandable cylindrical elements 12. Each pair of the interconnecting elements 13 on one side of a cylindrical element 12 are preferably placed to achieve maximum flexibility for a stent. In the embodiment shown in FIG. 4 the stent 10 has three interconnecting elements 13 between adjacent radially expandable cylindrical elements 12 which are 120 degrees apart. Each pair of interconnecting elements 13 on one side of a cylindrical element 12 are offset radially 60 degrees from the pair on the other side of the cylindrical element. The alternation of the interconnecting elements results in a stent which is longitudinally flexible in essentially all directions. Various configurations for the placement of interconnecting elements are possible, and several examples are illustrated schematically in FIGS. 7–10. However, as previously mentioned, all of the interconnecting elements of an individual stent should be secured to either the peaks or valleys of the undulating structural elements in order to prevent shortening of the stent during the expansion thereof.

FIG. 10 illustrates a stent of the present invention wherein three interconnecting elements 12 are disposed between radially expandable cylindrical elements 11. The interconnecting elements 12 are distributed radially around the circumference of the stent at a 120-degree spacing. Disposing four or more interconnecting elements 13 between adjacent cylindrical elements 12 will generally give rise to the same considerations discussed above for two and three interconnecting elements.

The properties of the stent 10 may also be varied by alteration of the undulating pattern of the cylindrical elements 13. FIG. 11 illustrates an alternative stent structure in which the cylindrical elements are in serpentine patterns but out of phase with adjacent cylindrical elements. The particular pattern and how many undulations per unit of length around the circumference of the cylindrical element 13, or the amplitude of the undulations, are chosen to fill particular mechanical requirements for the stent such as radial stiffness.

The number of undulations may also be varied to accommodate placement of interconnecting elements 13, e.g. at the peaks of the undulations or along the sides of the undulations as shown in FIGS. 5 and 11.

In keeping with the invention, and with reference to FIGS. 4 and 12–14, cylindrical elements 12 are in the form of a serpentine pattern 30. As previously mentioned, each cylindrical element 12 is connected by interconnecting elements 13. Serpentine pattern 30 is made up of a plurality of U-shaped members 31, W-shaped members 32, and Y-shaped members 33, each having a different radius so that expansion forces are more evenly distributed over the various members.

As depicted in FIGS. 13 and 14, after cylindrical elements 12 have been radially expanded, outwardly projecting edges 34 are formed. That is, during radial expansion U-shaped members 31 will tip outwardly thereby forming outwardly projecting edges. These outwardly projecting edges provide for a roughened outer wall surface of stent 10 and assist in implanting the stent in the vascular wall by embedding into the vascular wall. In other words, outwardly projecting edges embed into the vascular wall, for example artery 15, as depicted in FIG. 3. Depending upon the dimensions of stent 10 and the thickness of the various members making up the serpentine pattern 30, any of the U-shaped members 31, W-shaped members 32, and Y-shaped members 33 can tip radially outwardly to form a projecting edge 34. It is most likely and preferred that U-shaped members 31 tip outwardly since they do not join with any connecting member 13 to prevent them from expanding outwardly.

The stent 10 of the present invention can be made in many ways. However, the preferred method of making the stent is to coat a thin-walled tubular member, such as stainless steel tubing, with a material which is resistive to chemical etchants, remove portions of the coating to expose underlying tubing which is to be removed but to leave coated portions of the tubing in the desired pattern for the stent so that subsequent etching will remove the exposed portions of the metallic tubing, but will leave relatively untouched the portions of the metallic tubing which are to form the stent. The coated portion of the metallic tube is in the desired shape for the stent. An etching process avoids the necessity of removing burrs or slag inherent in conventional or laser machining process. It is preferred to remove the etchant-resistive material by means of a machine-controlled laser as illustrated schematically in FIG. 6.

A coating is applied to a length of tubing which, when cured, is resistive to chemical etchants. "Blue Photoresist" made by the Shipley Company in San Jose, Calif., is an example of suitable commercially available photolithographic coatings. The coating is preferably applied by electrophoretic deposition.

To ensure that the surface finish is reasonably uniform, one of the electrodes used for the electrochemical polishing is a doughnut-shaped electrode which is placed about the central portion of the tubular member.

The tubing may be made of suitable biocompatible material such as stainless steel, titanium, tantalum, superelastic NiTi alloys and even high strength thermoplastic polymers. The stent diameter is very small, so the tubing from which it is made must necessarily also have a small diameter. Typically the stent has an outer diameter on the order of about 0.06 inch in the unexpanded condition, the same outer

diameter of the tubing from which it is made, and can be expanded to an outer diameter of 0.1 inch or more. The wall thickness of the tubing is about 0.003 inch. In the instance when the stent was plastic, it would have to be heated within the arterial site where the stent is expanded to facilitate the expansion of the stent. Once expanded, it would then be cooled to retain its expanded state. The stent may be conveniently heated by heating the fluid within the balloon or the balloon directly by a suitable system such as disclosed in a co-pending application Ser. No. 07/521,337, filed Jan. 26, 1990 entitled DILATATION CATHETER ASSEMBLY WITH HEATED BALLOON which is incorporated herein in its entirety by reference. The stent may also be made of materials such as superelastic NiTi alloys such as described in co-pending application Ser. No. 07/629,381, filed Dec. 18, 1990, entitled SUPERELASTIC GUIDING MEMBER which is incorporated herein in its entirety by reference. In this case the stent would be formed full size but deformed (e.g. compressed) into a smaller diameter onto the balloon of the delivery catheter to facilitate transfer to a desired intraluminal site. The stress induced by the deformation transforms the stent from a martensite phase to an austenite phase and upon release of the force, when the stent reaches the desired intraluminal location, allows the stent to expand due to the transformation back to the martensite phase.

Referring to FIG. **6**, the coated tubing **21** is put in a rotatable collet fixture **22** of a machine controlled apparatus **23** for positioning the tubing **21** relative to a laser **24**. According to machine-encoded instructions, the tubing **21** is rotated and moved longitudinally relative to the laser **24** which is also machine controlled. The laser selectively removes the etchant-resistive coating on the tubing by ablation and a pattern is formed such that the surface of the tube that is to be removed by a subsequent chemical etching process is exposed. The surface of the tube is therefore left coated in the discrete pattern of the finished stent.

A presently preferred system for removing the coating on the tubing includes the use of an 80-watt CO_2 laser, such as a Coherent Model 44, in pulse mode (0.3 mS pulse length); 48 mA key current and 48 W key power with 0.75 W average power, at 100 Hz; Anorad FR=20; 12.5 Torr; with no assist gas. Low pressure air is directed through the fine focus head to ensure that no vapor contacts the lens. The assist gas jet assembly on the laser unit may be removed to allow a closer proximity of the fine focus head and the collet fixture. Optimum focus is set at the surface of the tubing. Cured photo-resist coating readily absorbs the energy of the CO_2 wavelength, so that it can be readily removed by the laser. A coated 4-inch length of 0.06 inch stainless steel tubing is preferred and four stents can be patterned on the length of tubing. Three tabs or webs between stents provide good handling characteristics for the tubing after the etching process.

The process of patterning the resistive coating on the stent is automated except for loading and unloading the length of tubing. Referring again to FIG. **6** it may be done, for example, using a CNC-opposing collet fixture **22** for axial rotation of the length of tubing, in conjunction with a CNC X/Y table **25** to move the length of tubing axially relative to a machine-controlled laser as described. The entire space between collets can be patterned using the CO_2 laser set-up of the foregoing example. The program for control of the apparatus is dependent on the particular configuration used and the pattern to be ablated in the coating, but is otherwise conventional.

This process makes possible the application of present photolithography technology in manufacturing the stents. While there is presently no practical way to mask and expose a tubular photo-resist coated part of the small size required for making intravascular stents, the foregoing steps eliminate the need for conventional masking techniques.

After the coating is thus selectively ablated, the tubing is removed from the collet fixture **22**. Next, wax such at ThermoCote N-4 is heated to preferably just above its melting point, and inserted into the tubing under vacuum or pressure. After the wax has solidified upon cooling, it is reheated below its melting point to allow softening, and a smaller diameter stainless steel shaft is inserted into the softened wax to provide support. The tubing is then etched chemically in a conventional manner. After cutting the tabs connecting the stents any surface roughness or debris from the tabs is removed. The stents are preferably electrochemically polished in an acidic aqueous solution such as a solution of ELECTRO-GLO #300, sold by the ELECTRO-GLO CO., Inc. in Chicago, Ill., which is a mixture of sulfuric acid, carboxylic acids, phosphates, corrosion inhibitors and a biodegradable surface active agent. The bath temperature is maintained at about 110–135 degrees F. and the current density is about 0.4 to about 1.5 amps per in.^{2} Cathode to anode area should be at least about two to one. The stents may be further treated if desired, for example by applying a biocompatible coating.

While the invention has been illustrated and described herein in terms of its use as an intravascular stent, it will be apparent to those skilled in the art that the stent can be used in other instances such as to expand prostatic urethras in cases of prostate hyperplasia. Other modifications and improvements may be made without departing from the scope of the invention.

Other modifications and improvements can be made to the invention without departing from the scope thereof.

What is claimed is:

1. A longitudinally flexible stent for implanting in a body lumen, comprising:

a plurality of cylindrical elements which are independently expandable in the radial direction and which are interconnected so as to be generally aligned on a common longitudinal axis;

a plurality of connecting elements for interconnecting said cylindrical elements, said connecting elements configured to interconnect only said cylindrical elements that are adjacent to each other; and

an outer wall surface on said cylindrical elements, said outer wall surface being smooth prior to expansion of said stent and forming a plurality of outwardly projecting edges which form as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter.

2. The stent of claim **1**, wherein said outer wall surface is substantially smooth when said stent in said first diameter configuration and said outwardly projecting edges form only as said stent is expanded radially outwardly from said first diameter to said second, enlarged diameter.

3. The stent of claim **1**, wherein said plurality of outwardly projecting edges extend radially outwardly from said outer wall surface and embed in the vascular wall of the body lumen in order to more firmly attach said stent to the vascular wall.

4. The stent of claim **1**, wherein said plurality of cylindrical elements include a plurality of peaks and valleys having a serpentine pattern.

5. The stent of claim **4**, wherein said plurality of peaks and valleys include a plurality of U-shaped members, a plurality

of Y-shaped members, and a plurality of W-shaped members, whereby a portion of said Y-shaped members forms said plurality of said connecting elements.

6. The stent of claim 5, wherein at least some of said plurality of said U-shaped members tip radially outwardly to form said outwardly projecting edges upon radial expansion of said stent.

7. The stent of claim 5, wherein at least some of said plurality of U-shaped, W-shaped, and Y-shaped members tip radially outwardly to form said outwardly projecting edges upon radial expansion of said stent.

8. The stent of claim 1, wherein said cylindrical elements are capable of retaining their expanded condition upon the expansion thereof.

9. The stent of claim 1, wherein said stent is formed of a biocompatible material selected from the group of materials consisting of stainless steel, tantalum, NiTi alloys, and thermoplastic polymers.

10. The stent of claim 1, wherein said stent is formed from a single piece of tubing.

11. The stent of claim 1, wherein said stent is coated with a biocompatible coating.

12. A longitudinally flexible stent, comprising:

a plurality of cylindrical elements which are independently expandable in the radial direction and which are interconnected so as to be concentrically aligned on a common longitudinal axis; and

a plurality of generally parallel connecting elements for interconnecting said cylindrical elements, said connecting elements configured to interconnect only said cylindrical elements that are adjacent to each other, so that said stent, when expanded radially outwardly, retains its overall length without appreciable shortening.

13. The stent of claim 12, wherein said cylindrical elements are capable of retaining their expanded condition upon the expansion thereof.

14. The stent of claim 12, wherein said radially expandable cylindrical elements in an expanded condition have a length less than the diameter thereof.

15. The stent of claim 14, wherein said stent is formed of a biocompatible material selected from the group consisting of stainless steel, tantalum, super-elastic NiTi alloys, and thermoplastic polymers.

16. The stent of claim 12, wherein said connecting elements between adjacent cylindrical elements are in axial alignment.

17. The stent of claim 12, wherein said connecting elements between adjacent cylindrical elements are circumferentially displaced with respect to said longitudinal axis.

18. The stent of claim 17, wherein the circumferential displacement of said connecting elements between adjacent cylindrical elements is uniform.

19. The stent of claim 12, wherein there are up to four of said connecting elements disposed between adjacent radially expandable cylindrical elements.

20. The stent of claim 12, wherein said radially expandable cylindrical elements and said connecting elements are made of the same material.

21. The stent of claim 12, wherein said stent is formed from a single piece of tubing.

22. The stent of claim 12, wherein the stent is coated with a biocompatible coating.

23. A longitudinally flexible stent for implanting in a body lumen, comprising:

a plurality of cylindrical elements which are independently expandable in the radial direction and which are interconnected so as to be generally aligned on a common longitudinal axis;

a plurality of connecting elements for interconnecting said cylindrical elements, said connecting elements configured to interconnect only said cylindrical elements that are adjacent to each other;

an outer wall surface on said cylindrical elements, said outer wall surface having a plurality of outwardly projecting edges which form as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter, whereby said stent does not substantially shorten upon expansion from said first diameter to said second, larger diameter.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,514,154
DATED : May 7, 1996
INVENTOR(S) : Lilip Lau, William M. Hartigan, John J. Frantzen

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 3, Line 3, Change "for", To read —form—.

Column 3, Line 41, Change "invention. When", To read --invention, when—.

Column 4, Line 46, Change "20", To read —10—.

Column 5, Line 53 and Line 55, Change "12", To read —13—.

Column 5, Line 54, Change "11", To read —12—.

Column 5, Line 63 and Line 67, Change "13", To read —12—.

Column 8, Line 33, Remove entire paragraph that begins with "Other".

Signed and Sealed this

Twenty-fourth Day of March, 1998

Attest:

BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademarks

EXHIBIT F

REDACTED

EXHIBIT G

REDACTED

EXHIBIT H

REDACTED

EXHIBIT I

REDACTED

EXHIBIT J

US005643312A

United States Patent [19]

Fischell et al.

[11] Patent Number: 5,643,312

[45] Date of Patent: Jul. 1, 1997

[54] **STENT HAVING A MULTIPLICITY OF CLOSED CIRCULAR STRUCTURES**

[76] Inventors: **Robert E. Fischell**, 14600 Viburnum Dr., Dayton, Md. 21036; **David R. Fischell**, 71 Riverlawn Dr., Fair Haven, N.J. 07704; **Tim A. Fischell**, 1018 Chancery La., Nashville, Tenn. 37215

[21] Appl. No.: **202,128**

[22] Filed: **Feb. 25, 1994**

[51] **Int. Cl.**[6] **A61M 29/00**

[52] **U.S. Cl.** **606/198**; 623/1; 623/12

[58] **Field of Search** 606/108, 191, 606/194, 195, 198, 200; 623/1, 12

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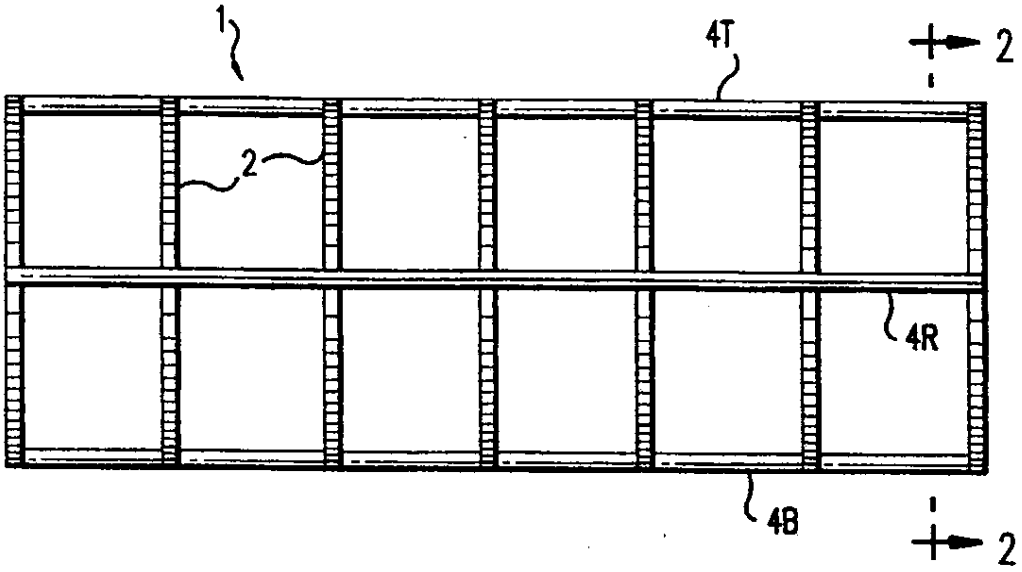
Primary Examiner—Michael Buiz
Assistant Examiner—William W. Lewis
Attorney, Agent, or Firm—Morton J. Rosenberg; David I. Klein

[57] **ABSTRACT**

The present invention provides for an expandable stent (1) for use in an artery or other vessel of a human body which forms a plurality of spaced apart generally circular rings (2). The stent structure (1) maintains patency of a vessel within which the stent (1) is inserted and is formed by a plurality of closed and generally circular rings (2) where the plane of each ring (2) is substantially parallel to the plane of an adjacent ring (2). The rings (2) have a common longitudinal axis generally perpendicular to the plane of each ring (2) with the longitudinal axis passing through the geometric center of each of the rings (2). A plurality of elongated wire structures forming longitudinals (4T, 4B, 4R, 4L) are fixedly secured to the rings (2) and extend in a direction generally parallel to the longitudinal axis of the rings (2). The stent (1) formed of the generally circular rings (2) optimizes hoop strength and minimizes elastic recoil of a vessel into which the stent (1) is inserted.

23 Claims, 4 Drawing Sheets



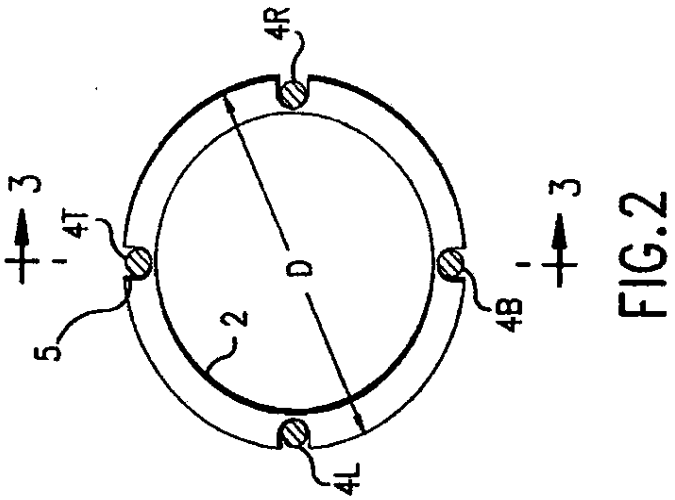


FIG.2

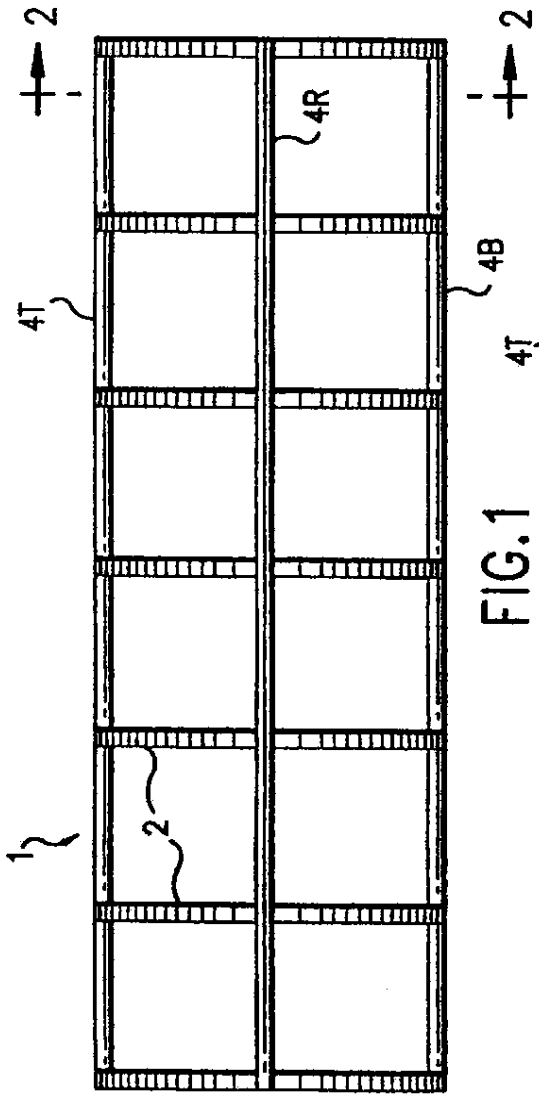


FIG.1

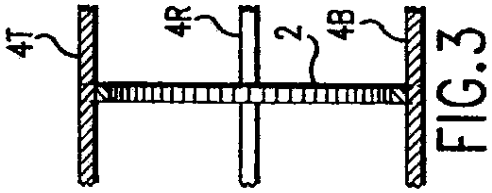


FIG.3

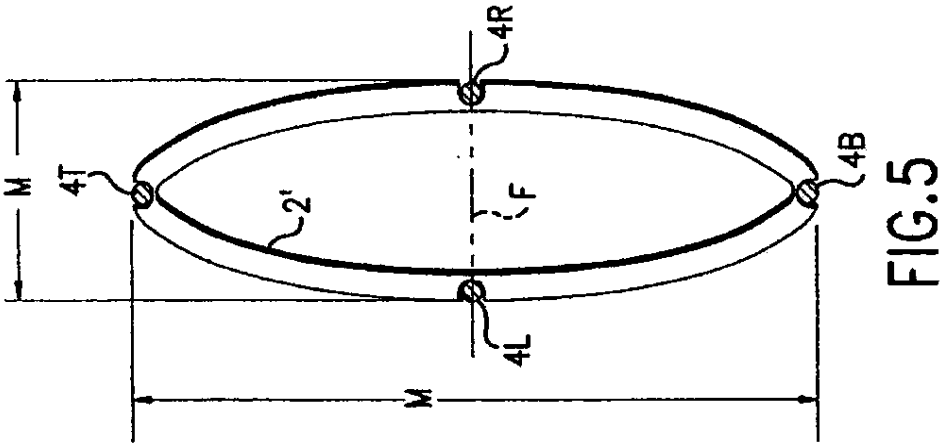


FIG.5

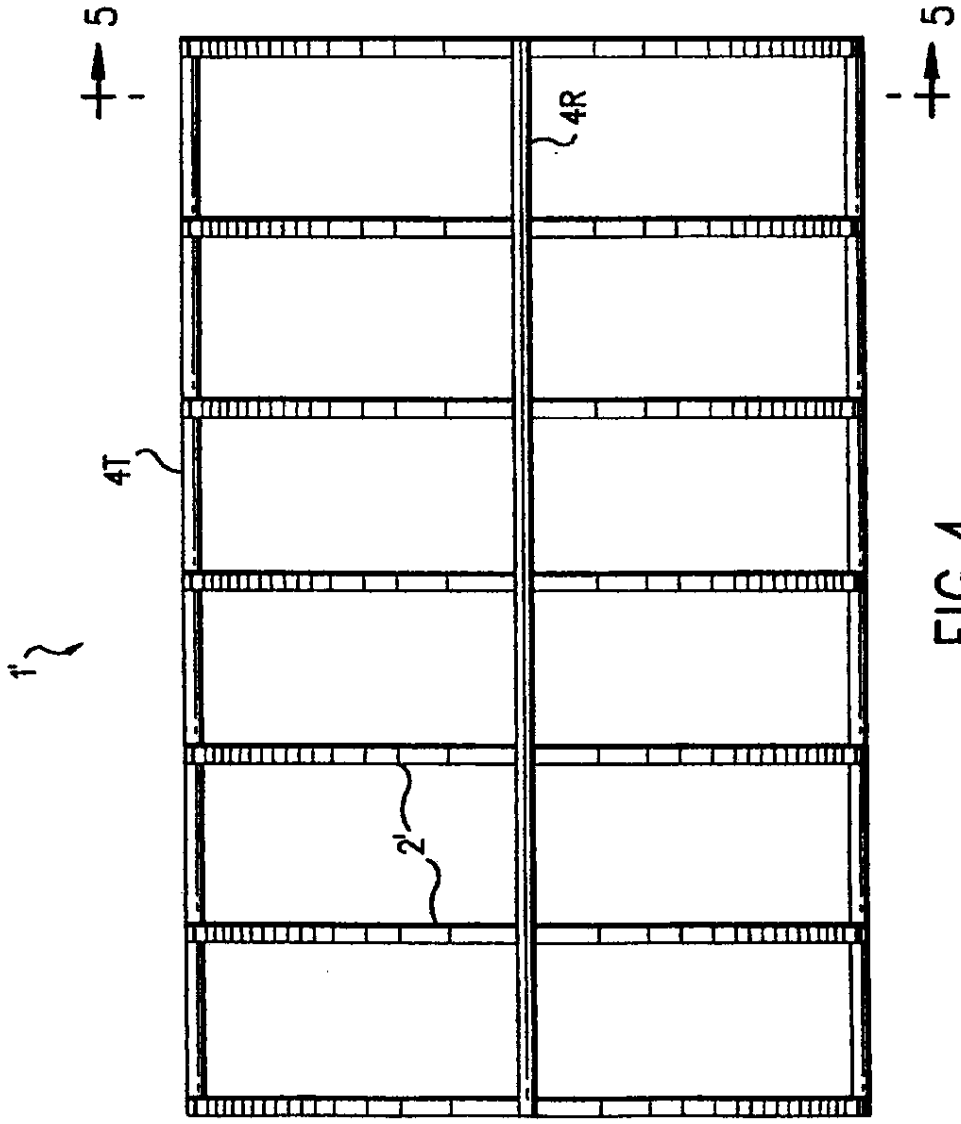


FIG.4

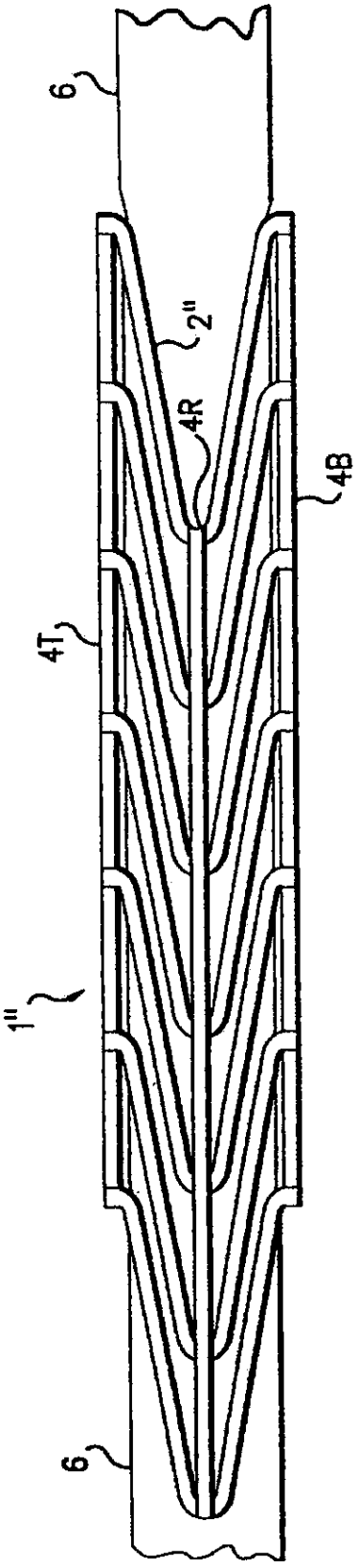


FIG.6

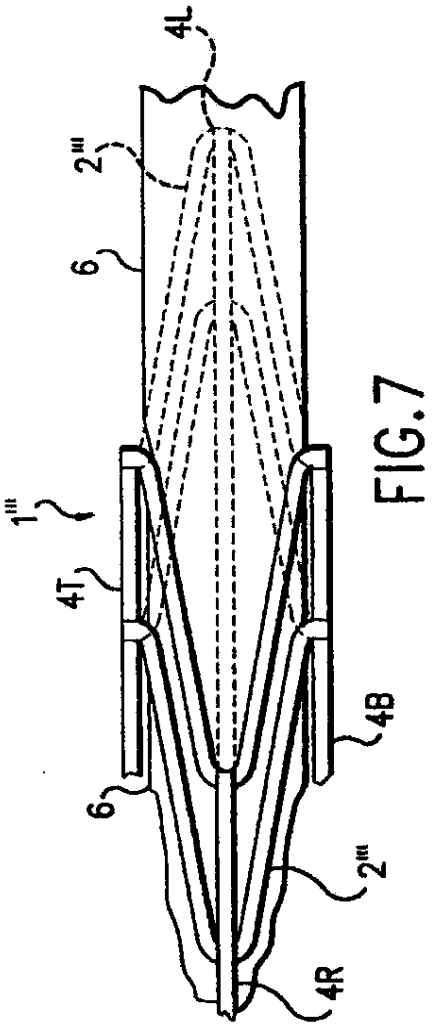


FIG.7

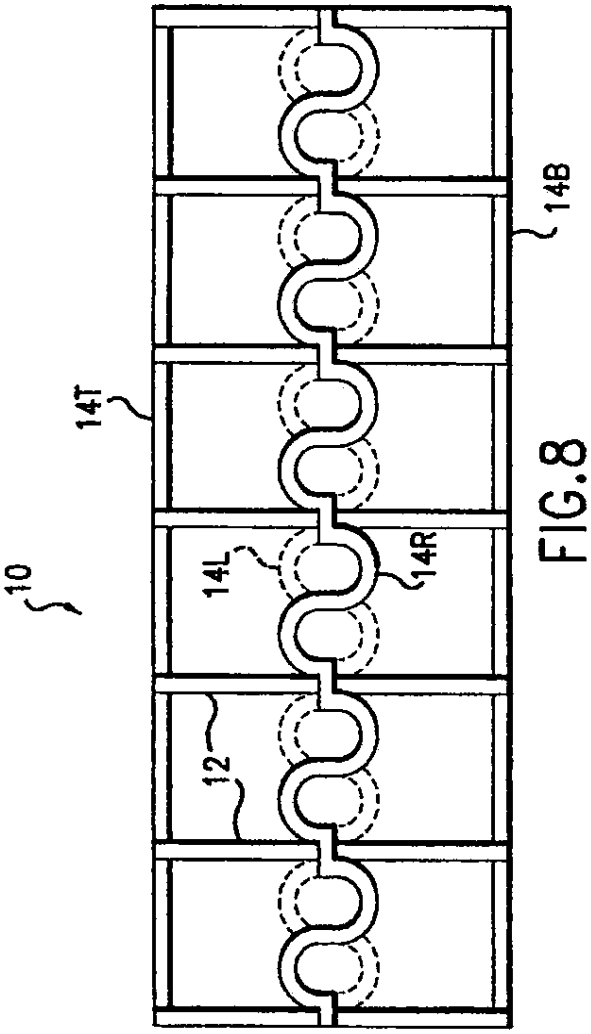


FIG.8

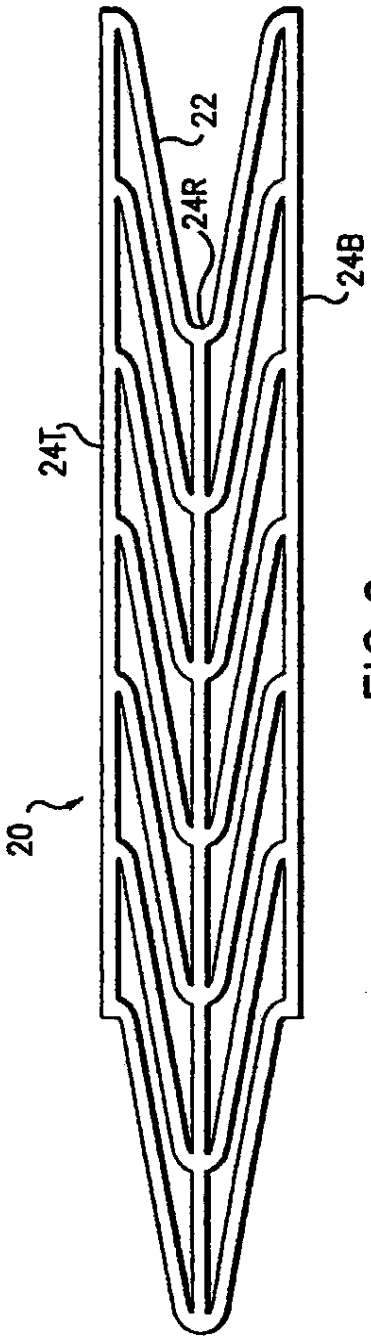


FIG.9

STENT HAVING A MULTIPLICITY OF CLOSED CIRCULAR STRUCTURES

FIELD OF THE INVENTION

This invention is in the field of stents for maintaining patency of any one of a multiplicity of vessels of the human body.

BACKGROUND OF THE INVENTION

In the last decade, many different designs of stents have been used to maintain patency of arteries and other vessels of the human body. In all such devices, hoop strength is an important characteristic. Specifically, the stent must have enough hoop strength to resist the elastic recoil exerted by the vessel into which the stent is placed. The Mass stent described in the U.S. Pat. No. 4,553,545 and the Dotter stent described in U.S. Pat. No. 4,503,569 are each open helical coils. The Palmaz stent described in the U.S. Pat. No. 4,733,665 is of the "chinese finger" design. The Gianturco-Rubin stent currently sold by Cook, Inc. is another stent design which like the stents of Mass, Dotter and Palmaz does not have any closed circular member to optimize hoop strength.

The ideal arterial stent utilizes a minimum wire size of the stent elements to minimize thrombosis at the stent site after implantation. The ideal arterial stent also possesses sufficient hoop strength to resist elastic recoil of the artery. Although the optimum design for maximizing hoop strength is a closed circular structure, no prior art stent has been described which has a small diameter when percutaneously inserted into a vessel and which expands into the form of multiplicity of closed circular structures (i.e. rings) when expanded outward against the vessel wall.

BRIEF SUMMARY OF THE PRESENT INVENTION

The present invention is an expandable stent that can be used in an artery or any other vessel of the human body which, when expanded, forms a multiplicity of generally circular rings whose closed structure optimizes hoop strength so as to minimize elastic recoil of the vessel into which the stent is inserted. Furthermore, the structure of the stent in the present invention is initially in the form of folded ellipses or ovals which can be formed to a small diameter for percutaneous insertion by means of a stent delivery catheter. The ovals are joined to each other by either a straight or undulating shaped wires which are called "longitudinals" which serve to space the deployed rings within the vessel. Straight longitudinals are used in straight vessels and undulating longitudinals can be employed in either straight or highly curved vessels such as some coronary arteries.

Thus, an object of this invention is to provide a stent having a maximum hoop strength by the employment of closed, generally circular structures which are in fact rings.

Another object of this invention is that the rings are initially in the form of ovals that can be folded to fit onto a cylindrical structure at a distal portion of a stent delivery catheter.

Still another object of this invention is that the fully deployed rings are spaced apart by means of longitudinals which are either straight of undulating wires that are placed to be generally parallel to the longitudinal axis of the vessel into which the stent is deployed.

Still another object of this invention is that the pre-deployment stent structure is formed as a single piece out of a metal tube having a smaller inside diameter as compared to the outside diameter of an expandable balloon onto which the pre-deployment stent is mounted.

These and other important objects and advantages of this invention will become apparent from the detailed description of the invention and the associated drawings provided herein.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side view of the stent after it has been deployed; i.e., in its post-deployment form.

FIG. 2 is a transverse cross section at section 2—2 of FIG. 1 illustrating how the longitudinals are joined to the rings.

FIG. 3 is a cross section at section 3—3 of FIG. 2 showing the joining of a single ring to the longitudinals.

FIG. 4 is a side view of the stent prior to being mounted onto a stent delivery catheter; i.e., in the form of an initial structure.

FIG. 5 is a transverse cross section at section 5—5 of FIG. 4 illustrating how the longitudinals are joined to the ovals.

FIG. 6 is a side view of a pre-deployment form of the stent structure in which the ovals have been folded into a small diameter cylinder that is placed around a deflated balloon situated near the distal end of a stent delivery catheter.

FIG. 7 is a partial side view of a pre-deployment stent structure showing only two of a multiplicity of folded ovals formed around an expandable balloon in which the ovals are folded in an alternative manner as compared with FIG. 6.

FIG. 8 is a side view of a post-deployment stent structure which utilizes two undulating longitudinals on opposite sides of the stent for improved placement in curved vessels.

FIG. 9 is a side view of a stent as etched out of a small diameter metal cylinder as a single piece of metal.

DETAILED DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side view of the cylindrical stent 1 of the present invention shown in its post-deployment configuration. The stent 1 has a multiplicity of rings 2 which are spaced apart by four wires called longitudinals. As seen in FIGS. 1 and 2, at the top of the stent is longitudinal 4T, at the bottom is longitudinal 4B, at the left side is longitudinal 4L and at the right side is longitudinal 4R. Although FIGS. 1 and 2 show 7 rings and 4 longitudinals, it is apparent that the stent can be made longer by adding rings or increasing the separation between rings. In a similar manner, the stent can be made shorter by reducing the number of rings or decreasing the spacing between rings. Also variable spacing of the rings is envisioned for accomplishing a variety of purposes including increased hoop strength at a particular section of the stent. Also, it is envisioned that the two or more longitudinals could be utilized for this stent design with a maximum number being 32.

FIGS. 2 and 3 illustrate the joining of the longitudinals to the rings. Specifically the longitudinals can be placed into cutouts in the form of notches 5 located on the outside perimeter of the ring 2. The longitudinals can then be spot welded, adhesively bonded or joined by any variety of means to the rings 2. It is also envisioned that the longitudinals could be placed on the inside perimeter of the ring 2, or holes could be mechanically or laser drilled through the ring 2 for placement therethrough of the longitudinals.

FIGS. 4 and 5 illustrate a stent 1' shown in one particular form in which it could be fabricated; i.e., in an initial structure form. Specifically, FIGS. 4 and 5 show that this

initial form of the stent 1' is a multiplicity of parallel ellipses or ovals 2' each oval having the same minor axis dimension m and major axis dimension M. The oval's minor axis passes through the center of the longitudinals 4L and 4R. The oval's major axis passes through the center of the longitudinals 4T and 4B. It is important to note that, if it is desired to have a final outside diameter D (as seen in FIG. 2) of the ring 2 after it is fully deployed, then it can be shown that D is given by the equation $D^2=½(m^2+M^2)$.

To place the stent design of FIGS. 4 and 5 onto a balloon that is mounted near the distal end of a stent delivery catheter, it is necessary to fold the ovals 2' around that balloon. Specifically, the pre-deployment cylindrical stent 1" can be formed onto an expandable balloon 6 as shown in FIG. 6 by folding the ovals 2' about the dotted line F (which is the minor axis of the oval 2') as shown in FIG. 5. Specifically, as seen in FIG. 4, the top and bottom of the ovals 2' could be held stationery while the side longitudinals 4R and 4L are pushed to the left which results in the pre-deployment structure which is shown as the stent 1" in FIG. 6. An optimum design has the folded ovals 2" as shown in FIG. 6 with the stent 1" being a cylinder whose outside diameter is equal in size to the minor axis dimension m. When the balloon 6 of FIG. 6 is expanded, the pre-deployment stent 1" structure forms the post-deployment stent 1 structure having circular rings 2 as shown in FIGS. 1 and 2.

The stent 1"' is an alternative embodiment for a pre-deployment structure of the stent of the present invention as it is placed onto a balloon. Specifically, FIG. 7 shows 2 folded rings 2"' of a multiple ring stent 1"'. The stent 1"' being formed by holding the top and bottom of the stent 1' of FIG. 4 stationery while pushing the longitudinal 4R to the left and pushing the longitudinal 4L to the right. Like the stent 1" of FIG. 6, when mounted onto a balloon, the stent 1"' has a cylindrical shape with a diameter equal to the dimension m.

FIGS. 1 to 7 inclusive illustrate stents that employ longitudinals that are formed from generally straight wires. FIG. 8 shows an alternative embodiment of a stent 10 that has two undulating longitudinals. Specifically, the left side longitudinal 14L (shown as dotted lines) and the right side longitudinal 14R are each undulating shaped longitudinals. A stent such as stent 10 could have two or more undulating longitudinals. Such a stent would bend more easily during insertion into a vessel and would be more readily adaptable for placement in curved vessels such as some coronary arteries.

Typically, the rings and longitudinals of the stents would be made of the same material. Typical metals used for such a stent would be stainless steel, tantulum, titanium, or a shape memory metal such as Nitinol. If Nitinol is used, the stent would be heat treated into the shape at body temperature having circular rings 2 as shown in FIGS. 1 and 2. The rings could then be distorted into ovals as shown in FIGS. 4 and 5 and then mounted onto a stent delivery catheter which does not employ a balloon but is of the more general shape described in the previously cited U.S. Pat. No. 4,553,545 by C. T. Dotter. Such a design would provide the desired stent structure having a multiplicity of generally circular rings instead of the Dotter design of a helical spring which inherently has a lesser hoop strength as compared to the present invention.

It should be understood that once the ovals are folded onto a stent delivery catheter, when they fully deploy, they do not form perfectly circular rings as shown in FIG. 2, but rather they are of a generally circular shape. Such comparatively small deviations from an exactly circular shape do not appreciably decrease hoop strength because they are in fact closed structures that are almost exactly circular.

It should also be understood that at least part of the end rings of the stent could be fabricated from or coated with a radiopaque metal such as tantalum or gold to provide a fluoroscopic indication of the stent position within a vessel. However, the other rings and the longitudinals could be made from a much less dense metal which would provide less obscuration of the central region within the stent. For example, the stent rings and longitudinals could all be fabricated from titanium or a titanium alloy except the end rings which could be formed from gold which is then plated with titanium. Thus, the entire outside surface of the stent would be titanium, which is known to be a comparatively non-thrombogenic metal while the gold in the end rings provides an improved fluoroscopic image of the stent extremities.

The dimensions of stent rings are typically 0.1 to 0.3 mm thick, with a width of 0.1 to 0.5 mm and an outside diameter D between 2.0 and 30.0 mm depending on the luminal diameter of the vessel into which it is inserted. The length of the stent could be between 1 and 10 cm. The wire diameter for the longitudinals would typically be between 0.05 and 0.5 mm.

Although the designs of FIGS. 1 through 7 inclusive illustrate separate longitudinals attached to a multiplicity of rings, this invention also contemplates an initial stent structure which is chemically etched from thin-walled tubing having an oval transverse cross section. Thus the oval and longitudinals would be formed from a single piece of metal thus precluding the need for attaching the longitudinals to the rings. In a similar manner laser or EDM machining could be used to form the stent from a thin-walled tube.

It is further anticipated that a pre-deployment stent structure 20 as shown in FIG. 9 could be formed from a thin-walled cylindrical tube whose inside diameter is slightly smaller than the outside diameter of the balloon 6 shown in FIG. 6. A pattern such as that shown in either FIG. 6 or FIG. 7 could be photoetched onto a thin-walled metal cylinder. The one piece structure 20 shown in FIG. 9 has folded ovals 22 and longitudinals 23T, 24B, 24R and (not shown) 24L. This pre-deployment stent structure 20 could then be mounted onto the expandable balloon; the stent having sufficient elastic recoil to firmly grasp down onto the balloon.

Various other modifications, adaptations, and alternative designs are of course possible in light of the above teachings. Therefore, it should be understood at this time that within the scope of the appended claims, the invention may be practiced otherwise than as specifically described herein.

What is claimed is:

1. A post-deployment stent structure for maintaining patency of a vessel of a human body comprising:

a multiplicity of closed and continuously formed, generally circular rings, the plane of each ring being generally parallel to the plane of each adjacent ring, the rings having a generally common longitudinal axis which is perpendicular to the plane of each ring, at least two of the rings being spaced apart from each other; and

a multiplicity of structures forming longitudinals, at least one longitudinal being fixedly attached to at least two of the rings and at least one longitudinal being adapted to maintain an essentially unchanged shape in the absence of the multiplicity of generally circular rings

and at least one of said longitudinals having an undulating shape for enhancing longitudinal flexibility of said post-deployment stent structure.

2. The stent of claim 1 wherein the longitudinals are generally elongated structures that lie generally parallel to the common longitudinal axis of the generally circular rings.

3. The stent of claim 1 wherein the rings are formed in unitary construction with the longitudinals from a single piece of metal.

4. The stent of claim 3 wherein the single piece of metal is generally in the form of a thin-walled cylinder.

5. The stent of claim 1 wherein the at least one longitudinal is spaced apart from all other longitudinals.

6. The stent of claim 1 wherein each longitudinal is spaced apart from every other longitudinal.

7. The stent of claim 1 wherein at least one of the longitudinals is a linearly directed, elongated structure.

8. The stent of claim 1 wherein all the longitudinals are of an undulating shape so as to enhance longitudinal flexibility.

9. The stent of claim 1 wherein the rings and longitudinals are made from titanium.

10. The stent of claim 1 wherein the multiplicity of circular rings has exactly two end rings which are those rings which have an adjacent ring on only one side and at least one interior ring which has adjacent rings on both sides, at least some portion of the end rings being formed from a metal having a higher density as compared to the density of the metal of the at least one interior ring.

11. The stent of claim 1 wherein the stent is formed from a metal having a shape memory characteristic.

12. An initial structure that is capable of being formed into a pre-deployment stent structure which in turn is capable of being deployed into a post-deployment stent structure for placement within a vessel of the human body, the initial structure comprising:

a multiplicity of flat ovals, the plane of each oval being generally parallel to the plane of all other ovals, the ovals having a common longitudinal axis which is perpendicular to the plane of each oval and which longitudinal axis passes through the geometric center of the ovals; and

a multiplicity of longitudinals which are fixedly attached to the ovals, the longitudinals being positioned onto the ovals so as to be generally parallel to the longitudinal axis of the ovals, at least one of the longitudinals being spaced apart from all other longitudinals and having an undulating contour for enhancing longitudinal flexibility of said initial structure.

13. The initial structure of claim 12 wherein the ovals and the longitudinals are unitary.

14. A pre-deployment stent structure which is capable of being deployed into a post-deployment stent structure for placement within a vessel of the human body, the pre-deployment structure being formed from an initial structure which consists of a multiplicity of flat ovals, the plane of each oval of said initial structure being generally parallel to the plane of all other ovals, the ovals also having a minor axis and a major axis and a minor axis dimension and a major axis dimension; the ovals having a common longitudinal axis which is perpendicular to the plane of each oval and which longitudinal axis passes through the geometric center of the ovals; and a multiplicity of longitudinals at least one of which is fixedly attached to at least two of the ovals, the longitudinals being of unitary construction with the ovals from a single metallic structure, at least one of said longitudinals having an undulating contour for enhancing longitudinal flexibility of said pre-deployment stent structure.

15. The pre-deployment stent structure of claim 14 wherein one side of the ovals is folded in one direction and the opposite side of the ovals is folded in the opposite direction to form a pre-deployment structure of a generally cylindrical shape.

16. The pre-deployment stent structure of claim 14 wherein the outer diameter of the generally cylindrical pre-deployment stent structure is approximately the same as the minor axis dimension of the oval.

17. A post-deployment stent structure for maintaining patency of a vessel of a human body comprising:

a multiplicity of closed and continuously formed, generally circular rings, the plane of each ring being generally parallel to the plane of each adjacent ring, the rings having a generally common longitudinal axis which is perpendicular to the plane of each ring, at least two of the rings being spaced apart from each other; and

a multiplicity of structures forming longitudinals, at least one longitudinal being fixedly attached to at least two of the rings, at least one longitudinal being spaced apart form all other longitudinals and at least one of said longitudinals having an undulating contour for enhancing longitudinal flexibility of said post-deployment stent.

18. a post-deployment stent structure for maintaining patency of a vessel of a human body comprising:

a multiplicity of closed and continuously formed, generally circular rings, the plane of each ring being generally parallel to the plane of each adjacent ring, the rings having a generally common longitudinal axis which is perpendicular to the plane of each ring, at least two of the rings being spaced apart from each other; and

a multiplicity of structures forming longitudinals, at least one longitudinal being fixedly attached to at least two of the rings, at least one longitudinal being adapted to maintain an essentially unchanged shape in the absence of any externally applied force, and at least one of said longitudinals having an undulating contour for enhancing longitudinal flexibility of said post-deployment stent structure.

19. A post-deployment stent structure for maintaining patency of a vessel of a human body comprising:

a multiplicity of closed and continuously formed, generally circular rings, the plane of each ring being generally parallel to the plane of each adjacent ring, the rings having a generally common longitudinal axis which is perpendicular to the plane of each ring, at least two of the rings being spaced apart from each other; and

a multiplicity of structures forming longitudinals, at least one longitudinal being fixedly attached to at least two of the rings, the longitudinals being of unitary construction with the generally circular rings from a single piece of thin-walled metal tubing and at least one of said longitudinals having an undulating contour for enhancing longitudinal flexibility of said post-deployment stent structure.

20. A post-deployment stent structure for maintaining patency of a vessel of a human body comprising:

a multiplicity of closed and continuously formed, generally circular rings, the plane of each ring being generally parallel to the plane of each adjacent ring, the rings having a generally common longitudinal axis which is perpendicular to the plane of each ring, at least two of the rings being spaced apart from each other; and

a multiplicity of structures forming longitudinals, at least one longitudinal being fixedly attached to at least two

of the rings and at least one longitudinal having an undulating shape so as to enhance the longitudinal flexibility of the post-deployment stent structure.

21. A predeployment stent structure adapted for placement in curved vessels of the coronary arteries, the stent structure being in the form of a thin-walled metal cylinder having a longitudinal axis, the stent including at least two undulating longitudinal structures each longitudinal structure having a multiplicity of straight sections and undulating sections with each straight section being joined continuously to at least one undulating section, the straight sections of all of the longitudinal structures being generally parallel to the longitudinal axis of the stent, the undulating sections of each longitudinal structure being of a generally curved shape so as to allow each undulating longitudinal structure to readily expand and contract in length when the stent is bent while passing through a curved coronary artery.

22. The deployment stent structure of claim 21 wherein each undulating section is in the general form of a sine wave.

23. A post-deployment stent structure for maintaining patency of a vessel of a human body comprising:

a multiplicity of closed and continuously formed generally circular rings, the plane of each ring being generally parallel to the plane of each adjacent ring, the rings having a generally common longitudinal axis which is perpendicular to the plane of each ring, at least two of said rings being spaced apart from each other and having a pair of opposing end rings positioned on opposing sides of at least one interior ring, at least a portion of at least one of said end rings being formed from a metal having a higher density as compared to the density of the metal of said at least one interior ring; and,

a multiplicity of structures forming longitudinals, at least one longitudinal being fixedly attached to at least two of the rings and at least one longitudinal being adapted to maintain an essentially unchanged shape in the absence of the multiplicity of generally circular rings.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

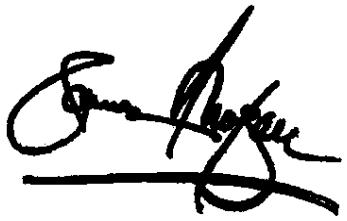
PATENT NO. : 5,643,312
DATED : July 1, 1997
INVENTOR(S) : Robert E. Fischell et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 4,
Line 47, insert the following sentence;
-- Another method to form the pre-deployment stent is by etching the correct pattern onto a thin, flat metal plate, then forming a tube from that plate and then making a longitudinal weld to form a cylindrically shaped structure which is, in fact, the pre-deployment stent structure 20 shown in Fig. 9. --

Signed and Sealed this

Twenty-fourth Day of December, 2002



JAMES E. ROGAN
Director of the United States Patent and Trademark Office